

IMPLEMENTATION AND REPLICATION OF EVIDENCE BASED SEXUAL  
REPRODUCTIVE HEALTH PROGRAMS

by  
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## ABSTRACT

**Background:** The state-wide scale up and replication of sexual reproductive health evidence based programs (SRH EBPs) in New Jersey provided an opportunity to study the implementation of six of these programs in different replication settings.

Implementation science is a developing field with a need for measurement testing of implementation measures. Additionally, implementation research is especially limited within SRH EBPs and with the adolescent population. One of the primary debates in the field as to whether strict adherence to the prescribed curriculum is essential, and whether adaptations negatively affect program outcomes.

**Data and Methods:** Psychometric testing was conducted on a participant responsiveness measure used on a state-wide survey across all six SRH EBPs, with 2,242 participants. In depth interviews were conducted with program implementers (n=18) of the same six SRH EBPs to further understand the contextual factors that implementation. Thematic analysis was used to identify successes and challenges to implementation of SRH EBPs.

An in-depth study on adherence and adaptations was conducted with one SRH EBP, with 1,608 participants (intervention and comparison). Developer-created fidelity logs were used as the data source for measurement of adherence and adaptations. Frequency calculations were used to describe adherence % and adaptation % by classroom.

Thematic analysis was used to categorize types and rationales for adaptations. Subgroups of adaptation levels were created among the intervention group who attended greater than 75% of sessions in order to determine program outcomes by level of adaptation.

Statistical analyses utilized propensity scores to increase comparability of intervention

adaptation subgroups and comparison participants. Program outcomes for each of these adaptation subgroups were determined using logistic regression analyses and mean differences.

**Results:** The refined factor structure of the participant responsiveness measure was reliable and valid among an adolescent population of varied age, gender, race, and invariant across multiple SRH EBPs and settings. Program implementers identified relationship building with partner sites and participants as strategies critical for implementation success. Program implementers, however, felt challenged in implementing some of these strategies, which involved adaptations, due to the perceived need to maintain fidelity to the program.

Frequency calculations indicated that adherence and adaptation varied considerably by classroom. Thematic analysis revealed that the adaptations made were related to delivery of content, rather than to the content itself, and were in response to participant needs and setting constraints. Propensity score matching successfully reduced significant differences in key covariates between intervention adaptation subgroups and the comparison group. Program outcomes comparing the intervention condition to the comparison condition for the low, middle, and high adaptation groups, respectively, were as follows: differences in SRH knowledge score intervention vs control [low=+14.3%, middle=+17.4% , high=17.8%], intent to use birth control in next 6 months [low: OR= 2.29 (1.28-4.09), p=.01; middle: OR= 2.36 (1.09-4.13), p=.01; high: OR= 5.67 ( 2.51-12.85), p=.00]; intent to abstain from sex [low: OR=1.63 (.80-3.30), p=.17; middle: OR=1.43 (.79-2.61), p=.23; high: OR=1.34 (.69-2.63), p=.37]; intent to use condoms in

the next 6 months [low: OR= 2.04 (1.11-3.76),  $p=.04$ ; middle: OR= 2.36 (1.09-4.13),  $p=.04$ ; high: OR= 5.67 (2.51-12.85),  $p=.04$ ].

**Conclusions:** Program outcomes did not appear to be reduced for the high adaptation subgroup. Quantitative and qualitative findings support the argument to allow for some flexibility in programs, as well as training for program implementers on how to make adaptations. It is important to include implementation in standard evaluation practice of EBPs in order to continue to understand replication findings, build the evidence base, and test program theory.

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## **INTRODUCTION & SPECIFIC AIMS**

In the nation's largest coordinated effort in adolescent sexual reproductive health (SRH), the Family Youth and Services Bureau (FYSB) and the Office of Adolescent Health (OAH) have provided roughly one billion dollars for the scale up and replication of SRH evidence based programs since 2009.<sup>1-3</sup> Evidence based programs have proven to positively change health behaviors through initial efficacy studies, however the evidence in replication settings is under-studied and is considered the "biggest gap in evidence".<sup>4</sup>

Given this funding effort, there is great opportunity for replication testing of the evidence based programs and for the investigation of the impact of implementation on program outcomes, particularly if there are null findings.<sup>4</sup> Implementation refers to both how a program is delivered (e.g. adherence, adaptations) as well as how it is received (e.g. participant attendance, participant responsiveness). Implementation can help explain null findings and/or differences in program outcomes between settings.<sup>5,6</sup>

There are three gaps in implementation research that this work addresses:

### **1) Measurement**

While there is strong empirical support that implementation affects program outcomes<sup>7-11</sup>, there is a lack of agreement on how to measure implementation constructs (as distinct from program outcomes).<sup>5,7,12</sup> An even more pressing need is to test the reliability and validity of current measures of implementation constructs.<sup>7,8,13,14</sup> This work contributes

to the literature by conducting psychometric testing on one implementation measure regarding how well a program is received, i.e. a construct of participant responsiveness.

## 2) Adherence and adaptation debate

There is a debate in the implementation and replication field as to whether adherence (also referred to as fidelity) is essential and whether adaptations negatively affect program outcomes.<sup>15</sup> Proponents of adherence suggest that higher levels of adherence result in greater program outcomes<sup>16–21</sup>, maintaining that adaptations are likely to be reactive and contribute negatively to program effectiveness.<sup>22,23</sup> Proponents of adaptations suggest that adaptations that respond to the local context, are necessary<sup>13,24</sup> and positively affect program outcomes.<sup>17,25,26</sup> Additionally, because implementation conditions in initial efficacy setting cannot be replicated exactly in subsequent settings, studies that measure adaptation unfailingly report adaptations during replication.<sup>7,22,27</sup> There has been a number of limitations in prior studies examining adaptations and adherence. Prior studies have calculated frequencies of adherence and adaptations, listed type of adaptations, or linked adherence/adaptation scores to program outcomes, but rarely have studies observed all three together.<sup>26,28–30 31,32</sup> Additionally, literature shows there are multilevel upstream contextual factors that activate program implementation and adherence and adaptations.<sup>6,7,13,33–37</sup> It is important to study the contextual factors that affect adherence and adaptation in the delivery of these programs, and from the perspectives of program implementers themselves. This study contributes to the literature by applying quantitative and qualitative methods to obtain a comprehensive picture of adherence and adaptations.<sup>38</sup>

### 3) Implementation research in adolescent sexual reproductive health

The studies that link implementation to program outcomes are mostly found in the substance use, mental health, and physical health fields, and focus primarily on adults<sup>7,39</sup>. Given the unique needs and developmental processes that take place during adolescence (ages 11-19), there is a need for implementation studies with a younger age group (11-19 years), the target population of this study. Additionally, implementation research is especially weak both among evidence based sexual reproductive health programs and in the field of sexual reproductive health more broadly.

This study aims to contribute to the literature by exploring the measurement properties of one implementation measure, addressing the adherence and adaptation, and highlighting the contextual factors that affect implementation of six SRH EBPs, implemented among adolescents, as a coordinated statewide effort in New Jersey. Both qualitative and quantitative methods are applied to obtain a comprehensive picture of implementation of evidence based sexual reproductive health programs.

### **Study Aims**

Aim 1: To assess the psychometric properties of survey questions capturing participant responsiveness to different adolescent sexual reproductive health programs in the United States. The Aim will be accomplished through the following steps:

A) Conduct a CFA on a random split-half sample to examine factor structure

*It is expected that 8 items will map onto two latent constructs: individual indicators of participant responsiveness and individual perception of group environment*

- B) Conduct a CFA on the second half of the sample to validate the factor structure
- C) Test measurement and structural invariance of the latent constructs between programs.

Aim 2: To explore program implementer perspectives on SRH EBPs they implemented regarding adherence and adaptations, and successes and challenges to implementation of evidence based programs, through in depth interviews.

Aim 3: To determine the frequency of adherence and the frequency, type and rationale for adaptations made in the implementation of a sexual reproductive health EBP, *Making Proud Choices*, and to estimate program outcomes of the intervention condition as compared to the comparison condition, as a function of level of adaptation (high/middle/low adaptations).

*Provided the type and rationale of adaptations made, program outcomes for intervention participants as compared to comparison participants will not appear to differ by level of adaptations i.e. participants in the high adaptation subgroups will not appear to have reduced program outcomes as compared to the low adaptation subgroups.*

To address and support these aims, this dissertation is structured into the following



chapters:

Chapter 2 provides an overview of adolescent sexual behavior, summarizes replication research and the evidence base for SRH EBPs, provides an overview of implementation terms and definitions, and concludes with an implementation framework that guided this work.

Chapter 3 describes the parent study from which this dissertation draws upon, the quantitative and qualitative measures used in this study, and the analytic methods for each of the study aims.

Chapter 4 uses quantitative data from six evidence based programs in this study to examine psychometric properties of a participant responsiveness construct, measured at post test among participants who received each intervention.

Chapter 5 interviews program implementers (i.e. program managers and facilitators) from the same six evidence based programs to better understand experiences implementing evidence based programs. Specifically, this chapter explores program implementer opinions on the evidence based program they delivered as well as implementation challenges and successes- providing insight into the fidelity adaptation debate.

Chapter 6 uses data from one evidence based program (*Making Proud Choices*) to both quantitatively and qualitatively explore the adherence-adaptation debate by describing

adherence and adaptation frequency, type and rationale for adaptation, and then determining the effect of levels of adaptation on program outcomes.

Chapter 7 summarizes findings from each of the research chapters and synthesizes these findings to discuss public health and research implications of this work.

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## **2. BACKGROUND AND SIGNIFICANCE**

### **2.1 Magnitude and Scope of Adolescent Pregnancy and Sexually Transmitted Infections (STIs)**

Adolescent pregnancy and birth rates have been declining since 1990, with the nation recording the lowest rates of adolescent pregnancy, abortion, and births in 2014.<sup>1,2</sup> In 2014, the United States witnessed a 9% decline in adolescent birth rates from 2013.<sup>2</sup> In 2014, 24.2 babies per 1,000 females ages 15-19 were born in the United States<sup>2</sup> ; most of these pregnancies were unintended and outside marriage.<sup>3</sup>

Despite the declines, having sex in high school is a norm; roughly 41.2% of students had heterosexual intercourse by the completion of high school.<sup>4</sup> Among sexually active students, 13.8% reported using no form of method to prevent pregnancy at last sex,<sup>4</sup> placing them at risk for sexually transmitted infections (STIs) as well as pregnancy. In fact, youth, ages 15-24, account for half of new STI infections, while comprising only 25% of the sexually active population.<sup>5</sup>

While adolescent pregnancy and birth rates have been declining, the disparity in adolescent pregnancy and birth rates persists. Race, ethnicity, geography, and socioeconomic status contribute to the disparity gap in teen pregnancy and births.

African American and Hispanic adolescent birth rates are more than double that of their white counterparts.<sup>2</sup> In addition, nearly half of all African American adolescents have an STI, which is double the rate of Hispanic and white counterparts.<sup>6</sup> Southern states have higher adolescent pregnancy, birth, and STD rates compared to their northern counterparts due, in part, to the lack of comprehensive sex education.<sup>7</sup>

When one looks at the outcomes of early childbearing, the impacts on mother and child are substantial and include school dropout, increased welfare dependence, low birth weight, increased chance of incarceration for the child, and poor educational and emotional outcomes for mother and child.<sup>8</sup> Consequences of early acquisition of STIs include increased risk for cervical cancer, infertility, death, infant illness and death, and reduced economic prosperity.<sup>9</sup> Societal costs are equally high. The National Campaign to Prevent Teen and Unplanned Pregnancy estimated the cost of adolescent births to taxpayers in 2010 at \$9.4 billion; however, the costs saved in the same year due to the decline in adolescent birth rates was \$12 billion.<sup>10</sup> This cost number includes costs for negative consequences for the children of adolescent mothers as well as health care costs, incarceration, foster care, and lost tax revenue. The medical costs of STIs for all sexually active Americans are roughly \$16 billion per year.<sup>11</sup>

## **2.2 Magnitude and Scope of Adolescent Pregnancy and STIs in New Jersey**

The geographical focus of this dissertation is New Jersey. Compared with many Southern states (i.e. Texas, Alabama, and Mississippi), New Jersey does not have a remarkably high adolescent pregnancy rate. It ranks thirty-second out of 50 states for adolescent pregnancy.<sup>12</sup> There are areas of New Jersey, however, such as Camden and Essex, with pregnancy and STI rates comparable to some of the highest in the nation.<sup>13</sup> Eight out of ten of adolescent pregnancies in New Jersey are unintended.<sup>3</sup> While adolescent pregnancy is relatively low compared to other states, abortion is not; New Jersey ranks third among states for adolescent abortions.<sup>12</sup>

## **2.3 Factors that Affect Adolescent Sexual Behavior**

Five hundred risk and protective factors have been identified in the literature as predictors of adolescent sexual behavior.<sup>14</sup> These factors are multilevel and consist of the following domains: individuals' biology, individual sexual values and behaviors, family life, peer and partner sexual values and behavior, and community.<sup>14</sup> Out of these factors, an individual's own sexual attitudes, beliefs, and intentions are most strongly linked to adolescent sexual behavior.<sup>15</sup>

## **2.4 Determining the Evidence for Sexual Reproductive Health Programs**

In 2007, Kirby assessed 115 evaluation studies of sexual reproductive health programs with following criteria: completed between 1990-2007, conducted in the US, sample size of at least 100 in intervention and control combined, targeted ages 18 and younger, used experimental or quasi-experimental design, employed appropriate statistical analyses, measured impact of sexual behavior, and had appropriate follow up time depending on behavior measured (6 months after intervention for initiation of sex and 2 months after intervention and for frequency of sex and condom use).<sup>14</sup> To be considered as having an effect, programs must have demonstrated a significant ( $p < .05$ ) change in sexual behavior. Program effects were found across all ethnic groups, all ranges of sexual experience, in different settings, and in programs that target non-sexual factors, sexual factors only, and both sexual and non-sexual factors. Kirby noted that program effects were quite modest, reducing risky sexual behavior by one third, and urged readers to



consider that sexual behavior works in a multilevel context of individual, family, peer, and community factors.<sup>14</sup>

Additional criteria were considered when assessing the strength of evidence: use of random assignment of participants, number of clusters assigned to intervention and control, attrition and response rates, measurement of STD/pregnancy rates, measurement of factors affecting behavior, publication of results, replication of studies, independent external evaluators, and sampling of programs.<sup>14</sup> In total, fifteen programs were deemed programs with “strong evidence of positive impact on sexual behavior or pregnancy or STD rates.”<sup>14</sup>

One of the challenges of “evidence-based programming” and “best practices” is that there are no consistent standards for strong evidence; and as a consequence, what one considers highest quality another might not. For example, when the Centers for Disease Control (CDC) published a “Compendium of HIV Evidence Based Programs”, it included *Be Proud Be Responsible*, yet Kirby did not include this program as best evidence.<sup>16</sup> Potential reasons for this, as noted by Kirby, were that the sample size in the evaluation study of *Be Proud Be Responsible* was small (150) and that the follow up did not allow for measurement of behaviors.<sup>14</sup> Another example of incongruence is that *Teen Health Project* was considered best evidence on Kirby’s list, yet was considered “good” on the CDC’s list, failing to meet “best” evidence because of <70% retention in both arms.

Three inclusion criteria for the most recent systematic review completed in 2011 by the Office of Adolescent Health were: quantitative analysis, measurement of program impact on pregnancy, STI, or sexual behaviors, and participants < 19 years of age.<sup>17</sup> Out of the 88 studies that met the inclusion criteria, 31 programs were considered effective. The quality of evidence was categorized as high, moderate or low. Characteristics of *high evidence* studies included: randomized control design, low attrition, no reassignment, no differences in timing of data collection between treatment and control, and at least two clusters to each condition of a cluster randomized trial. Characteristics of *moderate evidence* studies included: quasi experimental design or randomized control design that did not meet high evidence, equivalent program and comparison groups by age, gender, and race/ethnicity, one outcome measure (for participants >14 years of age), no differences in timing of data collection between treatment and control, and at least two clusters to each condition of a cluster randomized trial. The remaining studies were considered low evidence.

As evidenced by some of these incongruences, the strength of the evidence base depends on how you define it, rather than a term with universal meaning. While the line between high and moderate evidence differs depending on the review criteria, there is general agreement on what an effective program is among the systematic reviews.

## **2.5 Description of Evidence Based Models Implemented in New Jersey**

The New Jersey Department of Health released a request for proposals to implement evidence based sexual reproductive health programs as part of Personal Responsibility

Education Program in 2011. Implementing organizations selected one program to implement from a list of evidence based programs deemed as ready for widespread replication by the Office of Adolescent Health.<sup>17</sup> The evidence based programs provided information to adolescents on abstinence and contraception, as well as healthy relationships, attitudes and values about adolescent growth, financial literacy, parent-child communication and job success. **Table 1** provides a description of the evidence-based models that were included in this study and selected for replication by implementing organizations. Five of these programs directly target sexual factors only and one program (*Teen Outreach Program*) targets majority nonsexual factors through a service learning curriculum. Four programs included in this study met high quality evidence base ratings include: *Be Proud Be Responsible*, *Making Proud Choices*, *SiHLE*, and *Teen Outreach Program*. Two others met moderate quality standards: *Teen Health Project* and *Reducing the Risk*.

## **2.6 Replication Research for Sexual Reproductive Health Programs**

In the most recent systematic review, it was noted that the “biggest gap in the evidence is the lack of replication studies.”<sup>17</sup> Of the six programs in this study, only three have shown impact when replicated: *Teen Outreach Program*, *Reducing the Risk*, and *Be Proud Be Responsible*. The evidence for the remaining programs relies on the initial efficacy study alone, further illustrating the need for replication studies.<sup>17</sup> **Table 2** provides the evidence base thus far for each of the programs. Program outcomes vary between initial and replication studies of the same program and vary between programs by the type of SRH measure and quantity of the outcome.

**Table 1: Description of Evidence Based Programs Implemented in New Jersey**

Program Name & Developer	Goal	Theory of Behavior Change	Target Population	Content Core Components	Dosage	Setting
<b>Be Proud! Be Responsible!</b> Loretta Sweet Jemmott, John B. Jemmott III, & Konstance A. McCaffree	To provide adolescents with knowledge and skills to reduce risk of HIV, STIs and pregnancy. To delay initiation of sex. To reduce unprotected sex. To embody a sense of sexual responsibility, accountability, and pride when making sexual health decisions.	Social Cognitive Theory, Theory of Reasoned Action, Theory of Planned Behavior	Youth ages 13-18	Knowledge about HIV and AIDS Understanding Vulnerability to HIV Infection Attitudes and Beliefs about HIV, AIDS, and Safer Sex Building Condom Use Skills Building Negotiation and Refusal Skills	Six 50 minute modules It can be implemented in six sessions of sixty minutes each or in three 2-hour modules. In community settings, it can be implemented in a two-day format (3 hours each day), a six-day format (1 hour each day) or one-day (Saturday) for approximately five hours, plus time for serving lunch and snacks	School and Community
<b>Making Proud Choices!</b> Loretta Sweet Jemmott, John Jemmott III, & Konstance McCaffree	An adaptation of Be Proud Be Responsible for a younger population of youth (ages 11-13). It emphasizes abstinence, but also provides information on protection if the youth participant chooses to have sex.	Social Cognitive Theory, Theory of Reasoned Action, Theory of Planned Behavior	Youth ages 11-13	Getting to Know You and Future Orientation Consequences of STDS, Pregnancy, and HIV Attitudes and Beliefs about HIV and Condom Use Strategies for Preventing HIV Infection: Stop, Think, and Act Building Condom Use Skills Building Negotiation and Refusal Skills	Eight 1 hour modules. It can be implemented in two-day formats, four day formats, or 8 day formats. The developer recommends that the entire intervention be completed within 2 weeks if possible.	School and Community

<b>Reducing the Risk</b> ETR Associates	To prevent pregnancy, STD & HIV through attitude and skill building. This approach addresses skills such as risk assessment, communication, decision-making, planning, refusal strategies and delay tactics. The activities motivate students to take steps to avoid high-risk behaviors. Emphasis on experiential learning	Social Cognitive Theory, Social Influence Theory, Social Inoculation Theory	High school youth in grades 9 through 12, but especially recommended for grades 9 and 10.	Knowledge about STD, HIV, and pregnancy prevention, transmission, treatment and consequences. Perception of individual risk Social and peer norms Personal attitudes about abstinence, sex, and contraception. Self-efficacy and negotiation skills. Self-efficacy to obtain health care information and contraception from a clinic and use it. Communication skills	Sixteen 45-minute lessons. These lessons should be taught in sequence and last at least 45 minutes and taught 2-3 times a week. Classes are designed to be taught over a 3-week period.	School and Community (In school preferred)
<b>SiHLe</b> Ralph DiClemente et al.	A peer-led, group-level, social-skills training intervention designed to reduce sexual risk behaviors among African-American female teenagers who are at high risk of HIV. The program addresses relationships, dating and sexual health within the context of the female African-American teenage experience, emphasizing cultural and gender pride to give participants skills and motivations to avoid HIV/STDs	Social Cognitive Theory, Theory of Gender, and Power	Heterosexual African-American female teenagers between the ages of 14 and 18 who have had sexual intercourse and are at risk for HIV.	Knowledge in HIV transmission Negotiation skills (particularly condom use) Attitudes and norms about condom use Condom use building Understanding of healthy and unhealthy relationships Sense of empowerment and self-efficacy, based on cultural and gender pride	The program is delivered in four weekly 3 hour sessions with 6 month and 12 month follow up sessions.	Community

Program Name & Developer	Goal	Theory of Behavior Change	Target Population	Content Core Components	Dosage	Setting
<b>Teen Health Project</b> Kathleen Sikkema & Jeffrey A. Kelly	A community-level intervention that helps adolescents develop skills to increase abstinence and condom use, and prevent HIV risk behavior, using modelling, peer norm and social reinforcement, and a Teen Leadership Council approach.	Social Cognitive Theory, Diffusion of Innovation Theory	Adolescents from housing developments in urban areas with high poverty, STIs and Drug use.	HIV risk-reduction norms among peers, family members and the larger community HIV/AIDS knowledge (for parents) Communication approaches for abstinence and condom use (for parents) Behavioral Skills Development Contraceptive Education Self-Efficacy/Self-Esteem Sexuality/HIV/AIDS/STI Education	Two THP workshops, 3 hours each and are typically offered one week apart. Two follow-up sessions unscripted: 90-120 minutes each. Parent Education: 90 minutes. THP Leadership Council: 90 minutes each, weekly for six months	Community based low-income housing developments
<b>Teen Outreach Program</b> Brenda Hostetler	To create healthy behaviors, life skills, and a sense of purpose through a service youth development framework. Supportive relationships with adult facilitators and other peers is a crucial part of the model.	Service Learning	High school youth in grades 9-12 (disadvantaged and high-risk youth)	Relationships Values Communication and Assertiveness Influence Goal-Setting Decision-Making Adolescent Development and Sexual Health	25 sessions (minimum) of group meetings/curriculum 20 hours (minimum) of community service learning	School and Community

**Table 2: Evidence Base for Programs Implemented in New Jersey**

Program Name & Study rating as defined by OAH	Reference(s)	Efficacy Evaluation			Effectiveness Evaluation (s)		
		Population Evaluated	Setting Evaluated	Findings	Population Evaluated	Setting Evaluated	Findings
<b>Be Proud! Be Responsible!</b>  <i>High study rating</i>	<p>Jemmott JB, Jemmott LS, and Fong GT (1992). Reductions in HIV risk-associated sexual behaviors among black male adolescents: Effects of an AIDS Prevention Intervention. American Journal of Public Health 82(3): 372-377.</p> <p>1. Jemmott, J. B., Jemmott, L. S., Fong, G. T., &amp; McCaffree, K. (1999). Reducing HIV risk-associated sexual behavior among African American adolescents:</p>	<p>157 inner-city African-American male adolescents randomly assigned to receive intervention or a control intervention on career opportunities. Their ages ranged from 12 to 19, with a mean of 14.6 years.</p>	<p>School, outside of regular day in Philadelphia, PA</p>	<p>At post-test, participants in the intervention had greater AIDS knowledge, less positive attitudes on risky sex and less intent to engage in risky sex. At three months, participants in intervention group reported significantly less female sexual partners and fewer days of sex. Those who had sexual intercourse used condoms more consistently, and a smaller percentage of them reported engaging in anal intercourse. There were no significant findings for # of female anal sex partners or frequency of heterosexual anal sex.</p>	<p>2. 1, 357 9<sup>th</sup> and 10<sup>th</sup> grade students; 50% white, 36% black, 12% Hispanic; 52% female</p>	<p>2. 10 highschools in midsize metropolitan area in the Midwest</p>	<p>2. Positive impact on STD knowledge, and condom use knowledge as well as intent and beliefs; no impact on sexual initiation, frequency and condom use</p> <p>3. Findings were</p>

	<p>Testing the generality of intervention effects. <i>American Journal of Community Psychology</i>, 27(2), 161–187.</p> <p>2. Borawski, E.A., Trapl, E.S., Adams-Tufts, K., Kayman, L.L., Goodwin, M.A., &amp; Lovegreen, L.D. (2009). Taking Be Proud! Be Responsible! to the suburbs: A replication study. <i>Perspectives on Sexual and Reproductive Health</i>, 41, 12-22.</p> <p>3. Jemmott III, J. B., Jemmott, L. S., Fong, G. T., &amp; Morales, K. H. (2010). Effectiveness of an HIV/STD risk-reduction intervention for adolescents when implemented by community-based organizations: A cluster-randomized controlled trial. <i>American Journal of Public Health</i>, 100(4), 720-726.</p>	<p>1. 496 African American 7<sup>th</sup> and 8<sup>th</sup> graders. Mean age= 13.2 years randomized within age and gender stratifications to intervention or health promotion control group</p>	<p>1. School, outside regular day in Trenton, NJ</p>	<p>1. At post-test, intervention participants reported more positive beliefs about condoms, greater self-efficacy and stronger intent to use condoms. Participants in intervention group reported significantly lower frequency of unprotected sex and anal sex, less likely to have had anal sex, and had significantly fewer anal sex partners in last three months. No significant findings for having sex or for # sex partners in past 3 months.</p>	<p>3. 1,707 youth (male and female) ages 13-18, 90% African American were nested in CBOs, which were randomized to implement the intervention or a health promotion control.</p>	<p>. 86 community based organizations in New Jersey and Philadelphia, PA</p>	<p>averaged across 3, 6, and 12 mth follow ups. Adolescents sexually experienced at baseline had more consistent and frequent condom use in the past 3 months. No significant findings on frequency of sex in past three months or condom use at last sex.</p>
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<b>Making Proud Choices!</b>  <i>High study rating</i>	Jemmott, J. B., Jemmott, L. S., & Fong, G. T. (1998). Abstinence and safer sex HIV risk-reduction interventions for African American adolescents: A randomized controlled trial. <i>Journal of the American Medical Association</i> , 279(19), 1529–1536.	659 African American male and female adolescents in grades 6 & 7, with a mean age of 11.8 years were randomized to safer sex intervention, abstinence intervention, or general health issues control group (unrelated to sex behaviour).	Three middle schools in low-income area of Philadelphia, PA (on two consecutive Saturdays)	At three months, safer sex intervention participants reported more condom use at three months and higher frequency of condom use at 3, 6, and 12 month follow ups. Participants in intervention group who were sexually experienced at baseline were less likely to report unprotected sex in previous 3 months (remained significant at 6 and 12 month follow up) and reported lower frequency of unprotected sex (remained at six month follow up). These findings were not significant for those sexually inexperienced adolescents at baseline. There were no significant findings on overall rates of sex or frequency of sex at three or six months.	N/A	N/A	N/A
<b>Reducing the Risk</b>  <i>Moderate study rating for efficacy evaluation due to lack of random assignment to intervention and control</i>	Kirby, D., Barth, R. P., Leland, N., & Fetro, J. V. (1991). Reducing the risk: Impact of a new curriculum on sexual risk-taking. <i>Family Planning Perspectives</i> , 23(6), 253–263.  1. Hubbard, Betty M., Mark L. Giese, and Jacquie Rainey, "A Replication Study of Reducing the Risk, a Theory-Based Sexuality Curriculum for Adolescents," <i>Journal of School Health</i> , Vol.	758 high school students, majority in grades 9 & 10 assigned to treatment and control groups in quasi experimental design.	46 high school classrooms in rural and urban northern California	At 6 months, intervention participants had significantly increased knowledge and parent-child communication about abstinence and contraception. At 18 months, female participants inexperienced at baseline were less likely to report unprotected sex. No other significant effects were found at 18 months.	1. 532 high school students, majority in grades 10 & 11 and majority White	Five school districts in rural and urban areas of Arkansas were non randomly assigned to intervention and five assigned to control (regular health class)	At 18 months, intervention participants significantly reported delay in initiating sexual intercourse. Sexually active students significantly reported protected sex. There was a significant increase in parent-child communication about sex.

	68, No. 6, 1998, pp. 243-247.  2. Zimmerman, R. S., Cupp, P. K., Donohew, L., Sionean, C. K., Feist-Price, S., & Helme, D. (2008). Effects of a school-based, theory-driven HIV and pregnancy prevention curriculum. <i>Perspectives on Sexual and Reproductive Health</i> , 40(1), 42-51.				2. 1,944 ninth grade students, mostly between 14-15 years, majority White	17 high schools from KT and OH non randomly assigned to RTR, modified RTR, or school's preg/HIV curriculum	Intervention participants demonstrated short term improvement in knowledge. Participants in standard school HIV curriculum were significantly more likely to initiate sex than those in RTR interventions
<b>SiHLe</b>  <i>High study rating</i>	DiClemente RJ, Wingood GM, Harrington KF, et al. Efficacy of an HIV prevention intervention for African American adolescent girls. A randomized controlled trial. <i>JAMA</i> . 2004;292(2):171-179.	522 sexually experienced African American girls between the ages of 14-18 randomly assigned to intervention or control general health intervention	Four community health agencies in Birmingham, Alabama.	Intervention participants were more likely to report consistent condom use since intervention and at last sex at 6 <sup>th</sup> and 12 <sup>th</sup> month follow up. Over a 12 month period, intervention participants were less likely to have a new sex partner in the last 30 days and more likely to use condoms, had better condom use skills, higher % of condom use, fewer unprotected sex acts, and higher scores of mediators of HIV behaviors. They also reported fewer Chlamydia infections and self-reported pregnancies.	N/A	N/A	N/A
<b>Teen Health Project</b>  <i>Moderate rating due to high rates of sample attrition</i>	Sikkema, K.J., Anderson, E.S., Kelly, J.A., Winett, R.A., Gore-Felton, C., Roffman, R.A. et al. (2005). Outcomes of a randomized, controlled community-level HIV prevention intervention for adolescents in low-income housing developments. <i>AIDS</i> , 19, 1509-1516.	1,172 participants between ages of 11-18 randomized to a community-level intervention, skills workshop only intervention or control condition.	15 housing developments in Wisconsin, Virginia, and Washington in areas of high rates of STD and drug use.	At 12 month follow up, community-level intervention participants that were sexually inexperienced were more likely to remain abstinent than the control group. Participants in the community and skills workshop interventions were more likely to use condoms than participants in the control condition.	N/A	N/A	N/A

<b>Teen Outreach Program</b>  <i>High study rating</i>	<p>Allen, J. P., Philliber, S., Herrling, S., &amp; Kuperminc, G. P. (1997). Preventing teen pregnancy and academic failure: Experimental evaluation of a developmentally based approach. <i>Child Development</i>, 68(4), 729-742.</p> <p>1. Allen, J.P., Philliber, S. (2001). Who Benefits Most From A Broadly Targeted Prevention Program? Differential Efficacy Across Populations in the Teen Outreach Program. <i>Journal of Community Psychology</i>, 29, (6): 637-655.</p>	<p>655 high school students (mean age= 15.8), majority female (85%) and majority African American (67%) randomly assigned individually or by classroom to intervention</p>	<p>25 high schools in the United States.</p>	<p>Female intervention participants were less likely to report pregnancy. Intervention participants were at lower risk of school suspension and course failure.</p>	<p>1. 1,673 high school students, majority male (75.4%) compiled data from several studies (some randomly assigned, some not)</p>	<p>High school in the US</p>	<p>Intervention participants were less likely to report pregnancy. Intervention participants were at lower risk of school suspension and course failure. The intervention was most effective for those participants at highest initial risk for problem behaviors.</p>
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## 2.7 Implementation Research

Implementation refers to both how a program is delivered (e.g. fidelity, adaptations) as well as how it is received (e.g. participant attendance, participant responsiveness). For the purposes of the study here, four components will be discussed that comprise implementation: fidelity, adaptations, participant attendance, and participant responsiveness.

Implementation research can address a number of research questions: contextual factors that affect implementation, the relationship between implementation and outcomes, and the implementation process itself.<sup>18,19</sup> Until the 1990's, implementation research was largely nonexistent.<sup>20</sup> Instead, program evaluation focused on a program's efficacy, neglecting to measure the mechanism behind why a program might have or have not worked.<sup>20</sup> Since then, there has been effort to link implementation and program outcomes, however incorporating implementation into evaluation is not yet a standard practice.

The most extensive review of 500 studies on prevention programs for child and adolescent health (1976 to 2006) found that only 12% (n=59) of studies linked implementation to outcomes.<sup>21</sup> Of these, three quarters supported the positive association between implementation and outcomes.<sup>21</sup> In meta analyses of studies linking implementation to outcomes, implementation was found to be the most important factor related to positive outcome<sup>22-24</sup>, confirming the need to study implementation with program outcomes. The studies that linked implementation to outcomes were primarily

in the substance use, mental health, and physical health field. There was only one study in HIV prevention, confirming the need for measurement and linking of implementation to outcomes in sexual reproductive health.

One of the limitations of implementation research is lack of consensus on definitions and terms related to implementation as well as pressing need for reliability and validity testing of implementation measures.<sup>21</sup>

## **2.8 Components of Implementation**

### *Fidelity*

There are two main schools of thought regarding fidelity. In one school of thought, fidelity is defined as “fidelity of implementation (FOI)” and consists of the following five aspects: adherence (sticking to the core content), exposure (number and length of sessions implemented or dosage of program delivered), quality of delivery (way interactive methods were employed indicated by facilitator enthusiasm, confidence, communication, clarity of instructions), student responsiveness, and program differentiation.<sup>25–27</sup>

In the other school of thought, the dimensions of dosage, quality, participant responsiveness, and program differentiation are all considered as separate from fidelity, but part of the larger construct of implementation.<sup>21</sup> Fidelity, in this school of thought, is limited only to “adherence”- the “extent to which the innovation corresponds to the

originally intended program.”<sup>21,28</sup> The Centers of Disease Control defines fidelity as “faithfulness with which a curriculum or program is implemented; that is, how well the program is implemented without compromising its core components, which are essential for the program’s effectiveness.”<sup>29</sup> The Office of Adolescent Health (OAH) adopted the definition of fidelity for adolescent pregnancy programs as “maintaining the core components of the original program model.”<sup>30</sup>

What constitutes “core components” of fidelity also varies. Fixen<sup>31</sup> categorizes core components into context (what must be in place for a program to operate), compliance (core intervention components), and competence (skill of model deliverer). Century categorizes core components of fidelity into structural (knowledge and content) and instructional components (implementer actions and participant behaviors).<sup>28</sup> Mowbray categorizes core components of fidelity into structure fidelity (“framework for service delivery”) and process fidelity (“ways in which services are delivered”).<sup>32</sup> The Office of Adolescent Health categorizes core components of fidelity for adolescent pregnancy prevention programs into what was taught, how it was taught, and structural aspects of implementing the curriculum (i.e. dosage-how much was delivered).<sup>33</sup>

For the evidence based programs identified by the Office of Adolescent Health as ready for widespread use and replication, each developer identified the core components of the program. Core components identified span across several dimensions of implementation: adherence, exposure (dosage), and quality of sessions. As such, they are considered as fidelity, to maintain integrity of the intervention. Other aspects such as adaptations,

participant attendance, and student responsiveness can be assessed as aspects of implementation, not fidelity.

### *Adaptations*

The mix of fidelity and adaptation has been a source of much debate in replication research. Fidelity levels do not reach 100%, allowing for adaptations to have an important contribution to program outcomes.<sup>21</sup> Adaptation during the implementation process in the real world is expected, with some researchers emphasizing it is necessary to preserve effectiveness.<sup>34</sup> Others suggest adaptations are likely to be reactive, and contribute negatively to program effectiveness.<sup>35</sup> The difference in findings might be attributed to the way in which adaptations are defined. Like fidelity, *adaptation* has been defined in two predominant ways. In one, adaptations are defined as: any modification to a program model, inclusive of both modifications that make the program suitable for its context as well as modifications that reduce fidelity.<sup>36</sup> Adaptations are also defined as only modifications or additions to a program that make the program suitable for its context, rather than the lack of fidelity.<sup>29</sup> Adaptations may be made to the content delivered, the way in which the content was delivered, or in the system of delivery.<sup>36</sup> Adaptations may be planned or unintentional.

### *Participant Responsiveness and Participant Attendance*

Participant responsiveness can be defined as “levels of participation and engagement.”<sup>25</sup> This can be inclusive of both enthusiasm and interest of participants in the program as well as participation or attendance in the program. Attendance refers to the number of sessions attended.

## **2.9 Relationships among Implementation Components**

Higher levels of fidelity have been linked to greater program outcomes.<sup>37-42</sup> There are also some studies that reported no association between fidelity and program outcomes.<sup>43</sup> This can be explained by a few reasons. One might be the lack of variation in fidelity measures<sup>21</sup>. Lastly, as Berkel et al. suggests, implementation constructs are interrelated and work together to address program outcomes.<sup>44</sup> So, while fidelity might be high, if there is a lack of student participation or attendance, for example, program outcomes may not be achieved<sup>44,45</sup>.

Studies have found positive effects of adaptations on program outcomes.<sup>39,46,47</sup> Others have maintained that adaptation leads to a decrease in program outcomes.<sup>48</sup> This may be explained, in part, by variation in the definition of adaptation. Adaptations have also been linked to participant responsiveness.<sup>46</sup> One study noted that as fidelity decreased, participant responsiveness increased. In interviews following, it was determined that facilitators implemented strategies they felt were effective, eliminating strategies they felt were ineffective, consequently reducing fidelity, increasing adaptations, and increasing participant responsiveness.



## **2.10 Factors that Affect Implementation**

The positive association between implementation and outcomes begs the question, “What makes good implementation?” Much of the work on factors related to implementation suggests that the factors related to implementation are multilevel consisting of: participant, implementer (facilitator), implementing organization (grantee), program model, and community context.<sup>20,21,49,50</sup> Participant factors include baseline sexual risk factors and target population characteristics.<sup>49,50</sup> Implementer factors include motivation and attitudes toward the evidence based practice, belief in the intervention, self-efficacy and skill in delivering the intervention.<sup>49,51–54</sup> Program factors include the quality of materials and adaptability as well as ease of use.<sup>49</sup> Organization (implementing organization) level factors include leadership, priorities of the organization, a program champion, and shared decision making among staff.<sup>55</sup> Community or structural level factors can include laws or infrastructure as well as community support for the intervention.

## **2.11 Conceptual Framework**

There are several conceptual models in different disciplines that have been developed for implementation research.<sup>31,44,49,56,57</sup> The framework for the present study draws on two conceptual models.

The first model is that of Chen. Chen’s model demonstrates there is an action model of contextual multilevel factors: implementer (facilitator), curriculum, target population,

implementing organization (grantee), and community context.<sup>49</sup> This action model activates the behavior change model, which is the pathway by which an intervention produces behavior change and is based on program theory. Chen's model suggests that both implementation and the program theory must be successful in order to produce program outcomes. Chen also states that studying implementation allows an evaluator to more accurately understand what contributes to a program's success or lack of success.

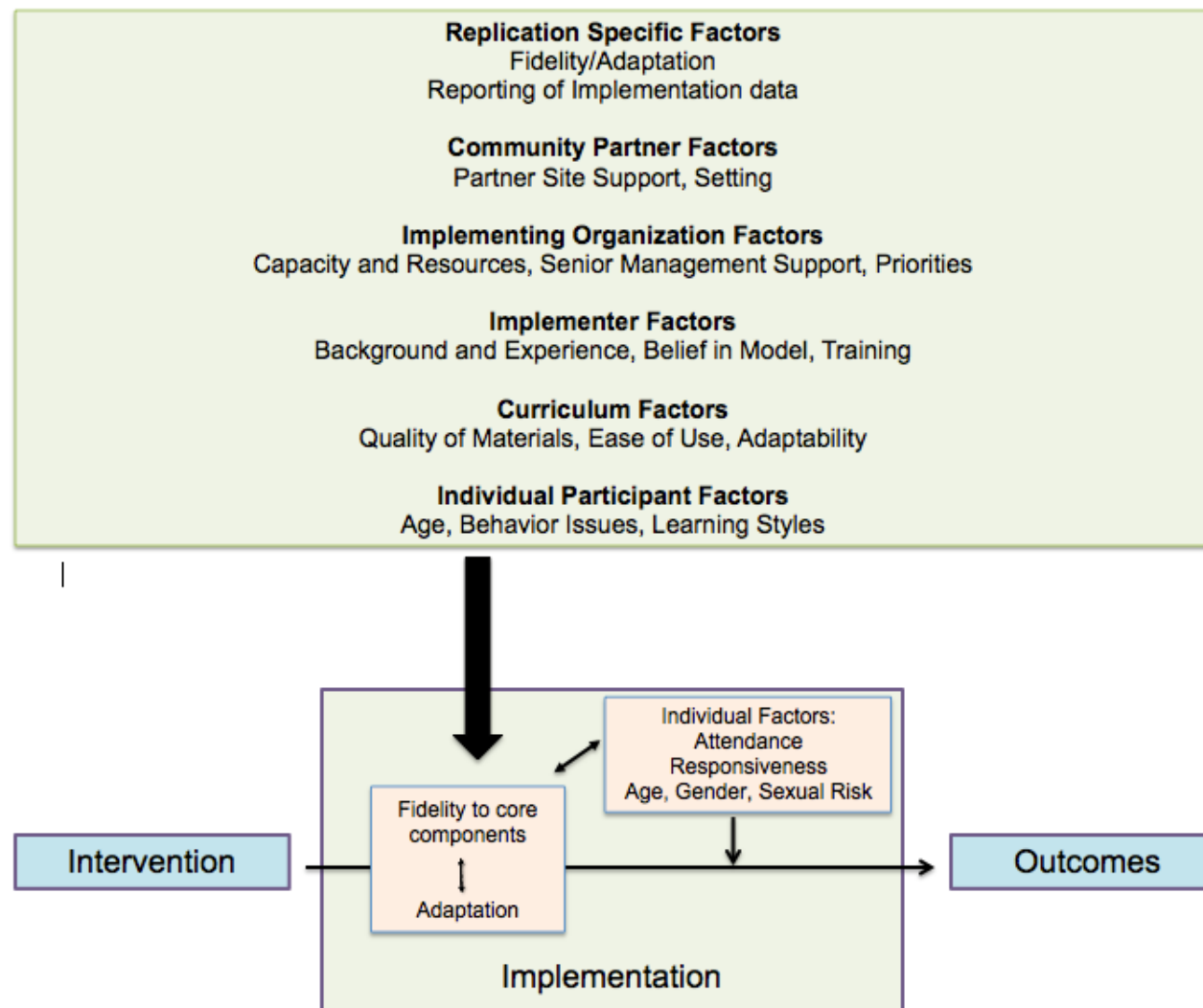
One of the limitations of Chen's models is that it does not address the specific components of implementation discussed in this chapter. For this reason, this study also draws upon Berkel's model, which displays the relationships between delivery implementation components (i.e. fidelity and adaptation) and participant receipt implementation components (i.e. attendance and responsiveness).<sup>44</sup> In Berkel's model, there is a direct relationship between fidelity and outcomes as well as between adaptations and outcomes. The relationship between fidelity and outcomes is moderated by participant responsiveness. Berkel hypothesizes that adaptations that take into account participants' needs are expected to increase participant responsiveness and program outcomes.

**Figure 1** is an implementation framework developed for evidence-based sexual reproductive health programs that melds aspects of the two models discussed above. This framework demonstrates that multilevel contextual factors activate and affect the quality of program implementation. Additionally, the model includes factors derived from the qualitative components of the present study that are specific to replication of evidence

based programs. This framework expands upon individual factors to include learning styles and individual behavior issues. This framework demonstrates the effect of the intervention on participant sexual reproductive health outcomes through implementation measures including: fidelity to core components, adaptations, participant attendance, and participant responsiveness. This study defines fidelity as adherence to developer-identified core components of the curriculum- as measures by a developer-created fidelity log. The fidelity log focuses on adherence to core content, and instructions on delivery of the core content are typically included in these logs as well. Core components of a curriculum may additionally include pedagogy and structural aspects of implementing the curriculum. While Berkel does not demonstrate the relationship between fidelity and adaptation, it is expected that this relationship is interactive to some extent, and that increased adaptations might result in less fidelity to the curriculum and vice versa, hence this model delineates a double arrow linking the two. Similar to Berkel's model, the strength of the relationship between fidelity and participant outcomes may depend on participant attendance and participant responsiveness. While Berkel's participant responsiveness measure includes both attendance and participant engagement measures as one measure, the model developed for this study differentiates between participant responsiveness and attendance. The reason for this is because there is less volition in adolescents when it comes to attendance- as implementation is typically conducted in a program (in school or after school) where attendance is often required. Fidelity and adaptations are expected to affect participant responsiveness and attendance. For example, adaptations that take into account participant needs and program context are expected to maintain or increase participant responsiveness and attendance. The

evidence based curricula in this study were designed to be interactive so adhering to core delivery components is also intended to increase participant responsiveness. There are other moderating factors such as age, gender, and risk behavior, which are outside of implementation components, and are not explored in this study, but are noted in the conceptual framework as affecting program outcomes.

**Figure 1: Implementation Framework for Evidence Based Sexual Reproductive Health Programs**



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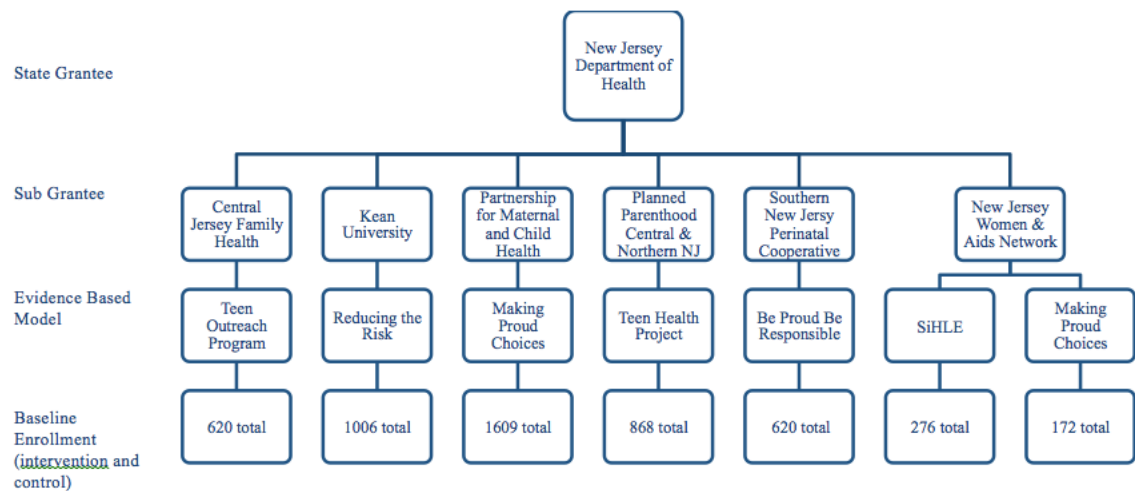
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### 3. METHODS

#### 3.1 Parent Study Overview

This implementation study was part of a larger quasi-experimental evaluation study conducted from 2013-2015. In the parent study, the Johns Hopkins Center for Child and Community Health Research (CCHR) evaluated six evidence-based sexual reproductive health programs implemented by six different implementing organizations as a part of the Personal Responsibility Education Program (PREP), with the New Jersey Department of Health (NJDOH). This federal initiative drew on the list of evidence-based sexual risk reduction programs that were deemed ready for widespread replication by the Office of Adolescent Health.<sup>1</sup> The NJ PREP program funded six organizations which selected six evidence-based programs: *Making Proud Choices*, *Teen Health Project*, *Teen Outreach Program*, *Reducing the Risk*, *Be Proud! Be Responsible!* and *Sisters Informing Healing Living Empowering*. Identified programs included information on abstinence and contraception, as well as healthy relationships, attitudes and values about adolescent growth, financial literacy, parent-child communication and job success. A requirement of funding was that at least half of program participants resided in communities of high teen pregnancy and STI prevalence. In total, the programs were implemented among 2,698 primarily African American and Hispanic adolescents, ages 10-19 years, in school and community-based settings. **Figure 1** indicates the program(s) each grantee delivered as well as the enrollment at baseline for each grantee, for the data collection cycle (August 2013- May 2015). The Johns Hopkins School of Medicine Institutional Review Board reviewed and approved all study protocols.

**Figure 1: Program and Baseline Enrollment by Grantee**



### 3.2 Study Design

The evaluation design included matched intervention and comparison groups. Each grantee was instructed to recruit comparison participants of similar age and gender as the intervention participants. At least 50% of total participants were recruited from top 30 municipalities identified as high risk for teen pregnancy (these municipalities together account for 59% of all New Jersey teen births). The study was implemented in schools or community based settings. Methods of comparison participant recruitment depended on the grantee (implementing organization). In some cases, comparison participants were recruited from the same school or community-based organization. In cases where recruitment from the same setting was not possible, a sister school or community based setting was used as a comparison. Participants in the comparison group received educational information on a non- sexual topic. Intervention participants received incentives for completion of three month follow up surveys. The incentive given to participants varied by grantee.

### **3.3 Data Collection**

The evaluation protocol included a survey administered by grantee study staff at pre, post, and three month follow up to assess sexual and reproductive health (SRH) knowledge, SRH behavioral intent, and SRH behaviors. The survey data was then manually entered into REDCap, an online data collection software, by grantee study staff, on a quarterly basis. The data entered into REDCap was stripped of personal identifiers; however, a unique participant ID was assigned to participants in order to link the surveys across measurement times. Only the grantee study staff had a secure document which linked the participant ID to participant name.

Adherence and adaptation data were captured on a fidelity log, which was created by the program developer. This log was specific to activities of the program and represented all required activities for the program. It was used for each classroom of students with which the intervention was delivered. The program facilitator who delivered the session completed the log within 48 hours after a session was delivered and this data was entered into REDCap. In order to limit social desirability bias, a training on how to fill out fidelity logs was conducted in which the following information was iterated verbally and in written form on the log: “We are looking for honest reports more than perfect reports as we are examining how both fidelity and adaptations work in the real world. Any adaptations, modifications, or changes to the curriculum should be described and explained in as much detail as possible. The more feedback provided, the more helpful these tools will be to us and future implementers.” In the training, program facilitators

were instructed to mark anything that deviated from the prescribed curriculum as a “change”. Fidelity logs have unique cohort ID. These cohort IDs were linked to participant IDs. Each fidelity log also contained the initials of the facilitator so that it was possible to link fidelity data to facilitator.

In-depth interviews were conducted with facilitators (n=11) of the curriculum (see Appendix I for Facilitator Interview Guide) and program managers (n=6) at each grantee organization (see Appendix II for Program Manager Interview Guide). All facilitators and program managers employed by the implementing organization and actively serving as either facilitator or program manager of the EBP at the time of the interview (n=20) were eligible for the study. NJDOH recruited potential study participants, introduced them to the study, and referred them to CCHR. Study participants were screened for eligibility by CCHR and provided written consent prior to the interview. Study participants were screened for eligibility and provided written consent prior to the interview (see Appendix III). Individual interviews were conducted via telephone or Skype (based on participant’s preference). All interviews were conducted by one female interviewer trained in qualitative methods (JP). The interviews were each approximately 45-60 minutes in length and were recorded using a digital audio recorder. Personal identifiers were collected for recruitment only and are limited to the following: first name, one phone number, and email address. No personal health information or personal identifiers were collected in the interview. In the event that names or other identifiers were disclosed during the course of a discussion or interview, this information was de-identified in the

transcription process. These data collection procedures were approved by the Johns Hopkins Bloomberg School of Public Health Institutional Review Board.

### **3.4 Instruments**

#### *Personal Responsibility Education Program Entry and Exit Survey (Pre and Post Test)*

The PREP pre and post surveys were required performance measure tools developed by Mathematica which contained standardized questions used across all programs and all participants. These OAH standardized pre and post survey measures were assessed for reliability and validity and were reviewed by a panel of experts<sup>2</sup>.

The pre survey contained 16 questions consisting of the following: demographic questions (questions 1-7), social-emotional competence scales of 4 items each (question 8 and question 16), intent to have sex (question 9), ever had sex (question 10), ever pregnant or gotten someone pregnant (question 11), number of times pregnant (question 12), number of sex partners in past three months (question 13), use of birth control (question 14), and use of condom (question 15). Additional questions were added to the entry survey by the JHU CCHR team in order to assess SRH knowledge and behaviors. In the pre survey, two scales were added to assess SRH knowledge. One scale assesses knowledge of behaviors that put an individual at risk for HIV. Another scale assesses methods to prevent STDs and pregnancy. An item measuring mother's education was also added as a proxy to assess for socio-economic status (SES). Lastly, two behavior questions were added (condom use at last sex and birth control use at last sex).

The post survey contained 10 questions consisting of the following: demographic questions (questions 1-6), social-emotional competence and future orientation scale of 13 items (question 7), behavioral intent to use contraceptives, have sex in the next 6 months or abstain from sex (question 8), participant responsiveness (question 9), and bullying (question 10). In the post survey, two scales were added to assess SRH knowledge, which are identical to the ones added in the entry survey. One scale assesses knowledge of behaviors that put an individual at risk for HIV. Another scale assesses methods to prevent STDs and pregnancy. Lastly, a question was added to assess type of contraceptive use planned. The post survey does not assess SRH behaviors. Because programs can last from 2 weeks to up to 9 months, evaluating behavior at post-test would likely not produce any results.<sup>2</sup>

The JHU CCHR team created a three month follow up survey to assess SRH behaviors. The follow up survey contains 11 questions. The first question is identical to question 7 on the post survey that measures social-emotional competence as well as future orientation and school connectedness. Questions 2-5 ask about the participants' sexual behavior in the past 3 months. Question 6 in the follow up is identical to question 8 in the post test that assesses behavioral intent to use contraceptives, have sex in the next 6 months or abstain from sex. Question 7 in the follow up is identical to the question on the post test that assesses type of contraceptive use planned for use. Questions 8-11 are identical to the entry and exit survey questions assessing SRH knowledge. The questions JHU CCHR team added were previously validated measures in the literature.



### *Fidelity Log*

Each program developer created a fidelity log that captured adherence to core content (as the developer sees it) of the curriculum. The fidelity log was comprised of ‘X’ activities (dependent on the curriculum); for which a facilitator marked 1) ‘completely finished activity’ 2) ‘finished activity with changes’ or 3) ‘did not finish activity’. The choices were mutually exclusive and a facilitator could not mark more than one option per activity. Each time a program facilitator marked ‘finished activity with changes’, a text box appeared prompting the facilitator to describe and explain rationale for changes made. If a log did not have this text box, CCHR modified the log to allow a blank space at the end of a set of activities for the facilitator to note any changes made to the core content and delivery of the program as well as the rationale for these changes. The language of each of these columns varied slightly between programs. The fidelity log for Teen Outreach Program did not have the same structure/format and was excluded for these analyses. Teen Health Project had only two column choices: ‘completed’ and ‘N/A’, but was modified halfway through the data collection cycle to include three choices to mirror the fidelity logs of other programs.

### *Interview Guide*

A semi structured interview guide was developed by JHU CCHR (JP) to collect data on contextual factors that might affect quality of implementation as well on implementation factors such as adaptations. JP developed all questions and pilot tested them for comprehension and clarity with facilitators and project managers of other projects at JHU CCHR, revised them based on pilot testing, and submitted them to the IRB as an

amendment. After approval of the amended interview guide, the interviewer used a semi-structured interview guide to facilitate discussion on the following topics: 1) background and experiences, 2) opinions and feelings on SRH EBPs, 3) adaptations, and 4) barriers and strategies in implementation. See Appendix I and Appendix II.

#### *Site Overview Form*

A Site Overview Form was developed by JHU CCHR (JP) to collect data on the number of program hours delivered. In this form, grantees provided a cohort ID for each cycle of program delivery with a cohort, the location of program delivery, and the date and time in which the program was delivered. The program manager and facilitator completed this form.

#### *Attendance Log*

Each grantee collected attendance data for each participant on a grantee specific attendance log. In this log, a participant ID was provided with the number of sessions each participant attended indicated and the date of each session delivery noted.

### **3.5 Quantitative Variables of Interest**

This section describes the variables used in the research paper chapters as well as in the appendices. The primary dependent variables were: SRH knowledge, SRH behavioral intent, & SRH behavior. There were four quantitative implementation variables measured in this study: adherence, adaptation, participant attendance, and participant responsiveness. Two of these variables (participant attendance and participant

responsiveness) were measured at the participant level. Adherence and adaptation were measured at the cohort level. The primary independent variable was receipt of the intervention, measured at the participant level.

*Primary dependent variables.*

*Sexual reproductive health knowledge* was measured at baseline and post test for intervention and comparison participants. A refined scale of 9 items were used to create a composite score of knowledge. Questions included 5 true/false items about behaviors that put you at risk for getting HIV (e.g. sharing needles for tattooing and piercing), 4 items regarding effective methods to protect people from STDs and pregnancy (e.g. douching) with three choice answers (Protects from Pregnancy & HIV/STD, Protects from Pregnancy Only, Protects from Neither). A composite knowledge continuous score was created for each individual, as percentage of items answered correctly out of the total number of items. Higher scores represented greater sexual reproductive health knowledge. Specific items are listed in Table 1 with bolded items representing items used in the final scale.

*Behavioral Intent* - questions were measured only at post test using a 5 pt Likert scale (much more likely to much less likely) for both intervention and comparison groups. Questions measuring behavior intent were: i) likely to use or ask a partner to use birth control in next 6 months ii) likely to use or ask a partner to use condoms in next 6 months iii) likely to abstain from sexual intercourse in next 6 months. These variables were

dichotomized (i.e. 1: more likely 0: same or less likely) in analyses to allow for easier interpretation with a logistic regression. For condom use and birth control intent, those who planned to abstain were dropped from the variable to look at intent among those who did not intend to abstain. The rationale for doing so was that intent to abstain would be coded in the same category as less likely to use contraception, which is different from abstinence. A sensitivity analysis was conducted including those who planned to abstain. See **Table 1** for items and dichotomization.

*SRH Behavior* –Five behaviors were assessed at three month follow up from last day of program delivery: i) ever had sex past 3 months (yes/no) ii) condom use at last sex (yes/no) iii) birth control use frequency (all of the time/most of the time/some of the time/none of the time). Birth control use was dichotomized for analyses for ease of interpretation. See **Table 1** for items and dichotomization.

#### *Implementation Variables*

*Attendance* – Attendance was measured as a percent of the number of sessions an individual attended out of the total number of sessions delivered by an implementer in a classroom. The total number of sessions delivered differed by classroom and program.

*Participant Responsiveness*- Participant responsiveness was assessed at post test on the last day of program delivery through participant self report. Eight items in total, were used to capture dimensions of participant responsiveness for teen pregnancy programs.

The first six items measured participants' interest in sessions (interest), clarity of material as perceived by the participant (material), usefulness of discussions as perceived by the participant (discuss), respect of the participant in the classroom (respect), bullying of the participant in the program (bully\_you), and participant ability to ask questions in the program (ask). The next two items assessed group environment, specifically participant perception of bullying of other youth due to sexual orientation (otherbully\_orient) and participant perception of bullying of other youth due to race/ ethnic background (otherbully\_race). Response categories were in the form of a five point Likert scale: 5= all of the time, 4= most of the time, 3= some of the time, 2= a little of the time, and 1= none of the time.

*Adherence* was measured as a percent of the number of times the program facilitator selected the box 'completely finished' out of the total number of activities offered.

*Adaptation* was measured as a percent of the number of times the program facilitator selected 'finished activity with changes' or 'partially completed' out of the total number of activities offered.

*Non-completion* or omission was measured as a percent of the number of times the program facilitator selected "did not finish activity" out of the total number of activities offered. For the purposes of this study, non completion or omission was not considered an adaptation, rather it was considered lack of fidelity.

### *Independent Variable*

*Receipt of Intervention-* A participant's status in the intervention or control group was noted by the participant ID and identified by distinct surveys in the REDCap system. A participant was assigned a value of "0" if in the control group and a value of "1" if in the intervention group.

### *Covariates*

*Demographics-* Demographics assessed include: age, ethnicity, race, gender, and SES.

*Baseline Risky Sexual Behavior-* Baseline risky sexual behavior included the following measures: if ever had sex, ever pregnant, baseline SRH knowledge score, sex in past three months, birth control use in past three months, condom use frequency in the past three months. Birth control use in the past three months and condom use in the past three months were recoded to make use of the full sample for matching. See **Table 1** for recoding.

Social Emotional Competence-measured as separate items and include resisted peer pressure, cared about school, shared with a parent or guardian, and managed conflict.

**Table 1: Measurement Variable Table indicating Question, Response Categories, Operationalization, and Source**

Variable	Question	Response Categories	Operationalization	Source
<b>Dependent Variables- measured for Intervention and Comparison participants</b>				
Knowledge of risky behaviors scale	Can the following behaviors put you at risk for HIV ? a) <b>Sharing needles for tattooing and piercing</b> b) <b>Having vaginal sex without a condom</b> c) Donating blood d) <b>Using the same condom twice</b> e) <b>Hugging</b> f) <b>Having anal sex without a condom</b>	Yes/No/Not Sure	Continuous (mean scale score)	PREP post survey
Knowledge of methods for prevention of pregnancy and STD scale	Which of the following methods are <u>effective</u> if used correctly to protect people from STDs (including HIV) and pregnancy? a) <b>choosing not to have sex (abstinence)</b> b) <b>Using hormone based birth control (e.g., the pill, Depo-Provera shot, patch, vaginal ring)</b> c) <b>Using condoms</b> d) using withdrawal e) <b>douching (washing out the vagina)</b>	Protects from Pregnancy & STD/HIV/ Protects from Pregnancy Only/ Protects from Neither		
Behavioral Intent	Would you say that being in the program has made you more likely, about the same, or less likely use or ask a partner to use birth control in next 6 months	Much more likely/Somewhat more likely/About the same/Somewhat less likely/Much less likely/ <i>I will abstain from sexual intercourse (choose not to have sex) in the next 6 months</i>	Dichotomized: 1: Much more likely/Somewhat more likely 0: About the same/Somewhat less likely/Much less likely	PREP post and 3 month follow up Survey

Behavioral Intent	Would you say that being in the program has made you more likely, about the same, or less likely to use or ask a partner to use condoms in next 6 months	Much more likely/Somewhat more likely/About the same/Somewhat less likely/Much less likely/ <i>I will abstain from sexual intercourse (choose not to have sex) in the next 6 months</i>	Dichotomized: 1: Much more likely/ Somewhat more likely 0: About the same/Somewhat less likely/Much less likely	PREP post and 3 month follow up Survey
Behavioral Intent	Would you say that being in the program has made you more likely, about the same, or less likely to use or ask a partner to use condoms in next 6 months likely to abstain from sexual intercourse in next 6 months.	Much more likely/Somewhat more likely/About the same/Somewhat less likely/Much less likely	Dichotomized: 1: Much more likely/ Somewhat more likely 0: About the same/Somewhat less likely/Much less likely	PREP post and 3 month follow up Survey
Behavior	Did you have sex in the past three months?	Yes/No	Dichotomous	3 month follow up survey
Behavior	In the past three months, with how many people did you have sexual intercourse, even if only one time?	1 person, 2-3 people, or 4 or more people	Dichotomized 1: 2 + 0: 1 person	3 month follow up survey
Behavior	When you had sexual intercourse in the past 3 months, how often did you or a partner use birth control?	All of the time/ Most of the time/ Some of the time/ None of the time.	Dichotomized 1: All of the time 0: Most, Some, None	3 month follow up survey
Behavior	The last time you had sex, did you or your partner use a condom?	Yes/ No/ Don't remember	Dichotomized 'Don't remember' coded as missing	3 month follow up survey
<b>Implementation Variables- measured for Intervention participants only</b>				
Attendance			Continuous (# of sessions attended/	Attendance Logs



			total # of sessions offered)	
Participant Responsiveness	<p>Did you feel interested in program sessions and classes?</p> <p>Did you feel the material presented was clear?</p> <p>Did discussions or activities help you to learn program lessons?</p> <p>Did you feel respected as a person?</p> <p>Were you picked on, teased, or bullied in this program?</p> <p>Did you have a chance to ask questions about topics or issues that came up in the program?</p> <p>Were youth in this program picked on, teased, or bullied because people thought they were lesbian, gay, bisexual, or transgender?</p> <p>Were youth in the program picked on, teased, or bullied because of their race or ethnic background?</p>	<p>5 pt Likert</p> <p>All of the time/ Most of the time/ Some of the time/ A little of the time/ None of the time</p>	Continuous (mean scale score)	PREP post survey
Fidelity subdomain: Core content	For each activity, indicate whether the activity was fully completed, completed with changes, or <u>not</u> completed. Place a check in the appropriate column.	Completed/ Completed with changes/ Did not complete	<p>Adherence= % core activities completed/ total core activities</p> <p>Adaptation= % core activities completed with changes/ total core activities</p>	Facilitator fidelity logs
<b>Independent Variables- measured for Intervention and Comparison participants</b>				
Intervention receipt		A value of "0" is assigned to participants in the comparison group and a value of "1" to participants in the intervention group	Dichotomous	

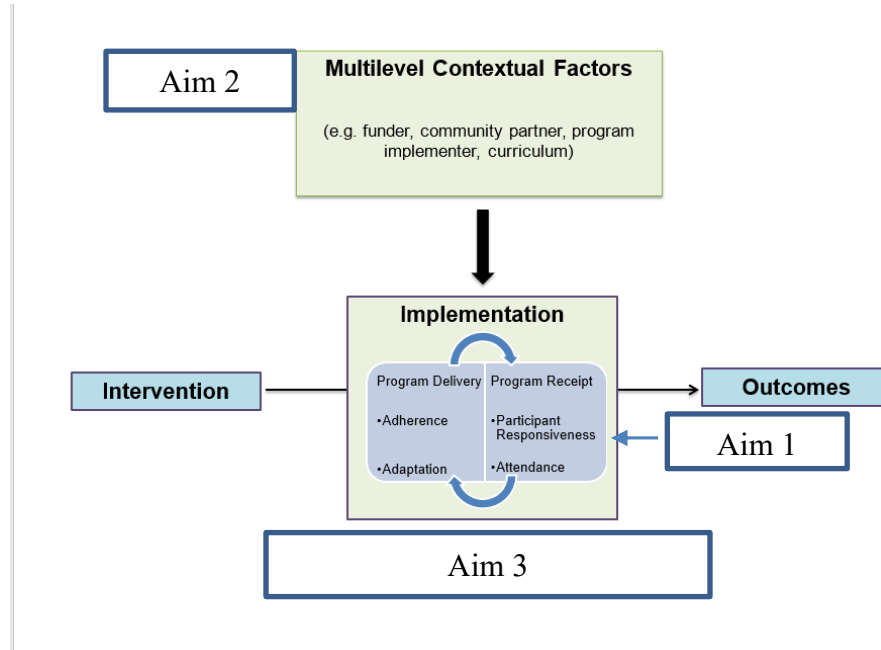
<b>Covariates- measured for Intervention and Comparison participants</b>				
Age	How old are you?	10/11/12/13/14/15/16/17/18/19/20/21+	Ordinal	PREP Pre Survey PREP Post Survey
Ethnicity	Are you Hispanic or Latino?	Yes/No	Dichotomous	PREP Pre Survey PREP Post Survey
Race	What is your race?	American Indian or Alaskan Native/ Asian/ Black or African American/ Native Hawaiian or Other Pacific Islander/ White or Caucasian	Categorical	PREP Pre Survey PREP Post Survey
Gender	What is your gender?	Male/ Female/ Transgender Male to Female/ Transgender Female to Male/ Prefer not to answer	Dichotomized Transgender Male to Female=female Transgender Female to Male=male Prefer not to answer=missing	PREP Pre Survey PREP Post Survey
Socioeconomic status (SES)	What is the highest grade or level of school completed by your mother or female guardian?	Less than High School Graduate/GED/ High School Graduate/GED/ More than High School Graduate/GED	Categorical	PREP Pre Survey
Knowledge of risky behaviors scale	Can the following behaviors put you at risk for HIV ? a) <b>Sharing needles for tattooing and piercing</b> b) <b>Having vaginal sex without a condom</b> c) Donating blood d) <b>Using the same condom twice</b> e) <b>Hugging</b>	Yes/No/Not Sure	Continuous (mean scale score)	PREP Pre Survey

Knowledge of methods for prevention of pregnancy and STD scale	<p><b>f) Having anal sex without a condom</b> Which of the following methods are <u>effective</u> if used correctly to protect people from STDs (including HIV) and pregnancy?</p> <p>a) <b>choosing not to have sex (abstinence)</b> b) <b>Using hormone based birth control (e.g., the pill, Depo-Provera shot, patch, vaginal ring)</b> c) <b>Using condoms</b> d) using withdrawal e) <b>douching (washing out the vagina)</b></p>	Protects from Pregnancy & STD/HIV/ Protects from Pregnancy Only/ Protects from Neither		
Baseline Sex	Have you ever had sexual intercourse?	Yes/ No	Dichotomous	PREP Pre Survey
Baseline Pregnancy	To the best of your knowledge have you been pregnant or gotten someone else pregnant even if no child was born?	Yes/ No	Dichotomous	PREP Pre Survey
Sex past three months	In the past three months, with how many people did you have sexual intercourse, even if only one time?	0, I did not have sex/ 1 person/ 2-3 people/ 4+ people	Dichotomized to indicate 'had sex in the past three months' 1: 1/ 2-3 people/ 4+ people 0: 0, I did not have sex	PREP pre survey
Condom use past three months	When you had sexual intercourse in the past 3 months, how often did you or a partner use a condom?	All of the time/Most of the time/ Some of the time/ None of the time	Ordinal recoded to indicate 'protected sex in the past three months' 1: All of the time 2: Most of the time/Some of the time 3: None of the time	PREP pre survey

			4: Did not have sex past three months	
Birth control use past three months	When you had sexual intercourse in the past 3 months, how often did you or a partner use birth control?	All of the time/Most of the time/ Some of the time/ None of the time	Ordinal recoded to indicate 'protected sex in the past three months' 1: All of the time 2: Most of the time/Some of the time 3: None of the time 4: Did not have sex past three months	PREP pre survey
Social-emotional competence	In the past three months, how often would you say you... a) cared about doing well in school b) shared ideas or talked about things that really matter with a parent/guardian c) resisted or said no to peer pressure? d) managed conflict without causing more conflict	5 pt Likert All of the time/ Most of the time/ Some of the time/ A little of the time/ None of the time	Ordinal a) recoded as 1: All of the time 2: Most of the time 3: Some of the time 4: A little/ None of the time	PREP pre survey

### 3.6 Analyses

Figure 2 represents the general analytic framework for this study.



All statistical analyses were conducted using STATA 12.0, R (MatchIt) software, and Mplus. All qualitative analyses were conducted using Atlas.ti software. All analyses were conducted in consultation with Dr. Jacky Jennings (PI), Dr. Robert Blum (advisor), Dr. Waylon Howard (CCHR Research Team), and Dr. Elizabeth Stuart (mentor).

#### *Aim 1 Analysis*

All SRH EBPs in the parent study were included in this analysis.

Psychometric testing of participant responsiveness measure involved the following steps:

- 1) CFA was conducted on a random split-half sample of the data to examine the factor structure,
- 2) A CFA was conducted on the remaining sample to validate the refined factor

structure, 3) A two-group CFA was used to test measurement and structural invariance of the latent constructs between programs. All data analysis were completed using MPlus7.3.<sup>3</sup> To conduct a CFA, complete data is required<sup>4</sup> therefore, Full Information Maximum Likelihood (FIML) was used in the Mplus 7.3 software program to deal with missing data. More specifically, to adjust for possible multivariate non-normality, the robust estimator option MLR was used for model estimation.<sup>3,5</sup>

### *Confirmatory Factor Analysis*

Based on previous research, the initial confirmatory factor analysis model included two latent constructs: 1) individual level indicators of participant responsiveness such as individual's interest in the session and 2) individual perception of group environment. We will primarily rely on confirmatory factor analysis (CFA) with means structures to evaluate the measurement properties of the responsiveness scale. CFA is an analytic technique that allows for the examination of observed and latent variables within a single group or across multiple groups.<sup>4</sup>

To develop and validate the proposed structure, the sample was randomly divided in half so that a CFA could be completed on the first half of the sample, and a subsequent CFA could be completed on the second half of the sample. For the CFA on the first half of the sample, the hypothesis was tested. The following fit statistics were used to determine appropriate fit: a) Root-Mean-Square Error of Approximation (RMSEA)<sup>6</sup>, (b) the Tucker Lewis Index (TLI)<sup>7</sup>, and the (c) Comparative Fit Index (CFI)<sup>8</sup>. Acceptable RMSEA

values are less than or equal to .08<sup>4</sup>, while values greater than .90 are considered acceptable for the NNFI, and the CFI.<sup>4,9,10</sup> TFI and CFI values above .90 demonstrated acceptable model fit and values above .95 demonstrated good model fit.<sup>7</sup> Based on model fit, items were adjusted or removed in the CFA to produce a better model fit. Once appropriate model fit was established, a second confirmatory factor analysis with a refined model was conducted on the second half of the sample to serve as a validity test.

#### *Multiple group confirmatory factor analysis*

A multiple group confirmatory factor analysis was conducted to determine how the factor structure held across different evidence based models.<sup>11</sup> For instance, the primary goal of this technique was to establish that the factor structure does not change as a function of the evidence based model so that comparisons of means of the construct across models are meaningful and true. This analysis was completed in three steps: 1) configural model testing and 2) testing the configural model with a less constricted model (loading invariance) and 3) to a more constricted model (intercept invariance). In the configural model, all factor means are fixed to zero, scale factors are fixed to one, and thresholds and loadings are unconstrained. For loading measurement invariance, factor loadings were set equal and tested. For intercept invariance, in addition, intercepts were set equal and tested. To assess significance of the comparison between models, the following statistics were observed: a) RMSEA value of the nested model is within the confidence interval range of the comparison model<sup>12</sup> and b) the difference in CFI between the nested model and the comparison model is no greater than .01.<sup>13</sup>

### *Omega Estimation for Scale Reliability*

The scale reliability was assessed using Coefficient Omega ( $\omega$ ) with a 95% Bias-Corrected Bootstrap confidence interval.<sup>14,15</sup> The omega estimation can be interpreted the same as Cronbach's alpha; however, it is a more accurate estimate because it does not assume all items carry equal loadings and variances, and can be used with hierarchical data.<sup>15,16</sup>

### *Latent Mean Differences Across Programs*

Once measurement invariance was established, a test of equivalence of latent variable means among programs was examined. An effects coding method<sup>17</sup> was used in Mplus to identify estimate the model and latent means. Then, the Satorra-Bentler Scaled Chi-Squared Difference Test ( $\chi^2_{SB}$ ) was used to determine if the means differ.<sup>18</sup>

### *Aim 2 Analysis*

All SRH EBPs in the parent study were included in this analysis.

All interviews were transcribed *verbatim*, reviewed for completeness, and de-identified before entry into Atlas.ti qualitative software<sup>19</sup> for coding of data. Interview transcripts



were coded and analyzed for emerging themes through an iterative process by two trained qualitative study team members (JP and VC).<sup>20</sup>

The two researchers coded the first six transcripts line-by-line together and through these initial discussions, developed a codebook. During this process, codes were created through discussion and consensus. The code name, definition, and how to apply the code were discussed and documented for each code. Next, two additional transcripts were coded separately using the initial codebook created by coding the first six transcripts. After two transcripts were coded separately, the two study team members met and reviewed each code in each transcript, reconciled any discrepancies through consensus, and adjusted the initial codebook as necessary to reflect the discussion.<sup>21</sup> They continued the coding process in a similar manner until all transcripts were coded. Any discrepancies in codes provided valuable discussion of the data and allowed for thoroughness in evaluating transcripts.<sup>21</sup> The two coders then co-developed the larger themes presented in this manuscript through an extensive discussion, with which they grouped codes into categories and examined the relationships of codes and categories to each other.<sup>20</sup>

### *Aim 3 analysis*

One SRH EBP from the parent study was included in this analysis. Data analysis procedures are described by subaim.

Objective 1: Using fidelity log entries, frequency calculations were conducted for three categories: adherence to core content, adaptation, and non-completion of core content.

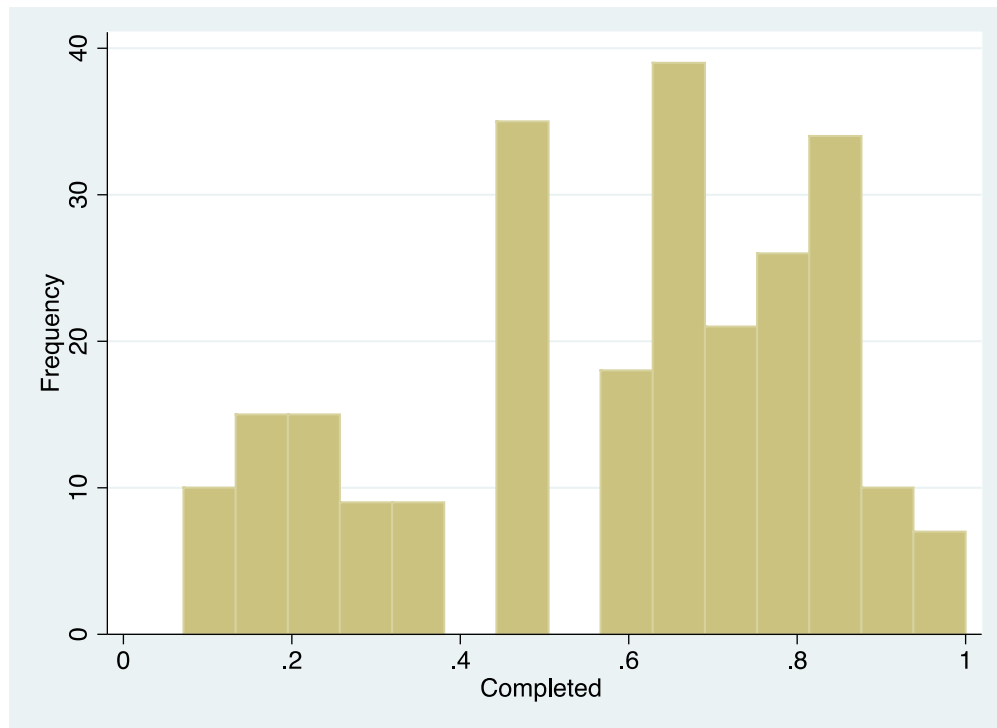
Objective 2: All fidelity logs were exported from REDcap and entered into Atlas.ti qualitative software. As mentioned earlier, fidelity logs provided free text space to indicate what adaptation was made and why. The qualitative adaptation data in the facilitator logs were first categorized by type of adaptation. For example, this might be shortening lessons, skipping warm ups, or adding in time for questions at the end of the session. Adaptations were also categorized based on rationale of adaptation. It was expected that the rationale for adaptations might shed light on if the adaptation was made as a response to participant needs (to make the program more suitable to context) or due to constraints of implementing the program. For example, if an activity was cut short, that might be considered an adaptation that would contribute to the lack of fidelity. However, if the rationale for the adaptation was that facilitators chose to skip an activity because he/she noticed that participants lose interest in the activity because it was not engaging in the session or historically in past sessions, then that would be considered an adaptation that addresses participant needs. Berkel et al emphasizes that this distinction is important in determining the relationship between adaptations and participant responsiveness, and subsequently program outcomes.<sup>22</sup> This free text space was coded and analyzed for emerging categories by two trained qualitative study team members through an iterative process of co-developing a codebook, coding transcripts independently, reconciling differences through discussion, and jointly developing categories.<sup>20,21</sup>.

Objective 3: Scale (item analysis) and reliability testing were conducted on two SRH knowledge scales (total of 11 items) related to pregnancy, HIV, and STI acquisition and protection. Item analysis indicated participants answered two items incorrectly at a much higher percentage (roughly 75% of participants answered these items incorrectly) than other items, so they were dropped from the scale. See **Table 1** bolded items for final set of items used. Cronbach's alpha, a coefficient of internal consistency, was used to estimate reliability.<sup>23</sup> The resulting scale had a reliability of .723, considered sufficient internal consistency.

To determine if adaptations had an effect on program outcomes, three subgroups were created: low adaptation (adaptation <25%), middle adaptation (adaptation between 25-50%), and high adaptation (adaptation >50%). These subgroups were chosen based on distribution of % adherence among classrooms. There is limited literature on adaptation levels and positive results, however adherence levels were documented so adherence was used as the cutoff. Durlak and Dupre's review of implementation literature report that positive results were found with fidelity levels between 60%-80%.<sup>24</sup> For this reason, the low adaptation/high adherence group was set as greater than 75% adherence, which can also be understood as less than 25% adaptation. To obtain cutoffs for the other two subgroups, the histogram and sample size was taken into consideration to create equal groups at natural cutoffs. See **Figure 2** for a histogram of adherence data. Because there was a natural break at 50% adherence- we used the cutoff of below 50% adherence (also

understood as >50% adaptation) and above 50% adherence and below 75% adherence (also understood as 25%-50% adaptation).

**Figure 3: Histogram of Adherence (core content fully completed) data for Making Proud Choices**



High participant attendance is statistically associated with greater participant program outcomes.<sup>25</sup> Given the link between attendance and program outcomes and the difference in mean attendance in each of the three subgroups, two analyses were conducted so to ensure program outcomes by adaptation subgroup were not affected by attendance in the subgroup: a primary analysis in which participants with less than 75% attendance or missing attendance (<10% missing) were excluded and a sensitivity analysis including all participants. Only participants in the intervention and comparison groups who completed the post test survey were included in analyses of post test outcomes

(knowledge/behavioral intent) (i.e. participants who did not answer post test were dropped from the analyses).

Propensity score matching methods were used to create comparability between adaptation subgroup participants and comparison participants.<sup>26,27</sup> The reason for using a propensity score approach was to account for individual characteristics that may make it more likely for a participant to be in a particular adaptation subgroup. Propensity score matching accounts for differences in observed covariates and relies on the assumption that the matching on observed covariates will also account for differences in unobserved covariates. Propensity score matching creates matched groups based on a number of covariates that have been condensed to a single propensity score.<sup>27</sup> A propensity score is defined as “the probability of being in the treatment [intervention] group given observed covariates.”<sup>28</sup> In this case, observed covariates used for matching included: all demographic variables (age/gender/race/ethnicity/mother’s education), baseline sex variables (ever sex/ever pregnant/baseline SRH knowledge score/sex in past three months/birth control use in past three months/condom use past three months), and baseline social emotional competence (resisted peer pressure/cared about school/shared with a parent or guardian/ managed conflict) because these covariates have demonstrated links to SRH outcomes in the literature.

To estimate the program outcomes for each subgroup, the following steps were conducted:

1. Fitted a propensity score model of an adaptation subgroup (low/medium/high adaptation) as a function of covariates, using the adaptation subgroup from the intervention group and the full comparison group.
2. Used full matching to match treatment group members to control group members with similar propensity scores. Full matching creates matched sets of intervention: control participants. For example, the intervention participant receives a weight of 1 and matched control units receive weights in proportion to the intervention participant so that the covariate distributions between the intervention participant and matched set of control participants are similar.<sup>29</sup> Full matching makes use of all the individuals in the data and has been shown to be effective at reducing bias due to observed confounding variables.<sup>27</sup>
3. Checked the standardized mean difference, indicating the balance of covariates in the matched intervention and comparison groups. If covariates had standardized differences greater than .20, they were controlled for in the outcome model.
4. Fitted a model of the outcome as a function of adaptation subgroup and covariates, with the full matching weights. Differences in mean knowledge score were calculated in addition to the outcome model.
5. Repeated steps 1-4 with remaining two adaptation subgroups

Less than 0.1% of fidelity data was missing and for these values, a value of “completed fully” was entered. Less than 6% of the outcome variables, among those who answered the post test, had missing data. Only variables for which outcome variables were observed were used in analysis.<sup>30</sup> Covariates were required to have a non-missing value

in R software prior to propensity score matching. Missingness for covariates ranged from 1%-22%. For covariates with missing values, the mean score of the covariate was imputed prior to propensity score matching. For variables with >10% missingness, a dummy variable was created for that variable (0/1) and included in the propensity score model so that patterns of *missingness* were matched in the propensity score analyses. Because the participants were nested within classrooms, clustering was accounted for at the classroom level to account for participant outcomes being correlated within a classroom. Classrooms were nested within schools, however clustering was accounted for at the classroom level because it was expected that participant outcomes would be more similar in classrooms than in schools because participants in the same classrooms were typically the same age, grade, academic level, and experience the same implementation of the program. For missing cases in the composite SRH knowledge score (this applied to 12% of the sample), in instances where 1-3 items in the scale were missing, the observed items were used to create the score. If a participant did not respond to more than three items in the scale, the entire composite SRH knowledge score was coded as missing (this applied to roughly 18% of the sample).

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#### **4. PSYCHOMETRIC TESTING OF PARTICIPANT RESPONSIVENESS MEASURES OF EVIDENCE BASED ADOLESCENT SEXUAL REPRODUCTIVE HEALTH PROGRAMS IN THE UNITED STATES**

##### **INTRODUCTION**

Assessing implementation of evidence-based programs is crucial to understanding how practical and effective such programs are in a natural or non-experimental setting.<sup>1,2</sup> In addition, assessing the implementation of a program sheds light on the mechanisms by which evidence based interventions produce or do not produce effects in natural settings.<sup>3</sup> There is strong empirical support that implementation affects program outcomes<sup>1,4-7</sup>, yet there is a lack of agreement on how to measure implementation outcomes (as distinct from program outcomes)<sup>1,3,8</sup>, and an even more pressing need to test the reliability and validity of current measures of such implementation outcomes.<sup>1,4,9</sup>

One implementation outcome is the “fidelity of implementation,” which is defined as the extent to which a program is executed as prescribed by design.<sup>10</sup> There are five dimensions in literature that constitute the larger construct of implementation fidelity.<sup>1,11</sup> The five dimensions are: participant responsiveness, adherence (sticking to the core content), exposure (number and length of sessions implemented or dosage of program delivered), quality of delivery (way interactive methods were employed indicated by facilitator enthusiasm, confidence, communication, clarity of instructions), and program differentiation.<sup>9-11</sup> These dimensions are applicable in any programmatic setting and could each represent independent measures of fidelity or could be assessed as a composite measure.<sup>11</sup> This paper focuses on participant responsiveness as one measure of fidelity of adolescent health programs in the United States. Participant responsiveness can

be defined as participant “levels of participation and engagement.”<sup>11</sup> This can be inclusive of enthusiasm and interest of participants in the program.<sup>4,10,12</sup>

Participant responsiveness is central to successful implementation; participants must engage or participate in the intervention for the intervention to produce effects.<sup>10,13</sup>

Adherence and participant responsiveness are conceptualized to have a bidirectional relationship; participant responsiveness has been conceptualized as both a moderator of adherence and program outcomes<sup>4,10</sup> and as a mediator between pre and post program outcomes.<sup>14</sup> Specifically, in adolescent pregnancy prevention programs, Kelsey and Layzer recently conceptualized participant responsiveness 1) as a moderator between adherence and program outcomes, 2) as a mediator between quality of service and program outcomes, and 3) as a mediator between adaptations and program outcomes.<sup>15</sup>

Participant responsiveness is measured in a variety of ways in adolescent health literature: facilitator report of student participation in program activities<sup>16</sup>, completion of homework assignments, attendance, and participant report of program satisfaction.<sup>17</sup>

Berkel conceptualizes participant responsiveness as multidimensional, including several of the indicators mentioned above.<sup>4</sup> Schoenfelder builds upon this work and tests the multidimensional construct of subjective participant responsiveness with a three-factor confirmatory factor analysis, resulting in the following dimensions and associated indicators at the individual level: participant liking of the program (measured by attendance, program satisfaction, skill helpfulness), skill use (measured by average home practice efficacy, average home practice fidelity, and frequency of skill use).<sup>14</sup> He also described indicators that operate at the group level, including perceived group

environment (measured by perceived group cohesion, perceived leader support, and perceived group expressiveness).<sup>14</sup>

A state-wide evaluation was conducted to evaluate the scale up and replication of SRH programs. The state-wide evaluation survey has included measures of participant responsiveness measured at post test that will be evaluated in this paper. Durlak and Dupre, Proctor et al, and Dusenbury all strongly emphasize the need for psychometric testing of measures of implementation outcomes, with a particular need for documentation of reliability and validity of these measures.<sup>1,9,18</sup> The objective of this study was to assess the psychometric properties of state-wide survey questions capturing participant responsiveness to different adolescent sexual risk reduction programs in the United States. Evidence based sexual risk reduction programs include: *Be Proud! Be Responsible, Sihle, Teen Health Project, Reducing the Risk, Making Proud Choices* (this was implemented by two different implementing organizations so will be labeled *Making Proud Choices 1* and *Making Proud Choices 2*), and *Teen Outreach Program*. In addition, this study examined if there were differences in mean participant responsiveness scores by evidence based program. It is hoped that this study will provide informative psychometrics regarding this tool in order to advance the measurement of implementation outcomes for adolescent health programs in the United States and similar settings.

## **METHODS**

### **Program Description**

The New Jersey Department of Health and Senior Services, Division of Family Health Services, awarded different grantees funds through the Personal Responsibility Education

Program to implement six different evidence-based sexual reproductive health programs throughout New Jersey (one model was implemented by two different implementing agencies). Grantees included local health departments, community based organizations, universities, and youth serving agencies. The Center for Child and Community Health Research at Johns Hopkins University was awarded the contract to evaluate the effectiveness of each model. This study employed a quasi-experimental design, using a comparison group for each implementation site. The evaluation included a survey that was administered at pre, post, and three month follow up. Participant responsiveness was assessed at post test in the intervention group. The post survey was prepared by Mathematica Policy Research.

### **Study population**

Male and female adolescents, ages 10-19, were recruited for program participation throughout New Jersey. At least 50% of adolescents were required to live in one of the state identified municipalities at high risk for teen pregnancy, sexually transmitted infections, and HIV/AIDS. The study sample was restricted to those participants who completed the participant responsiveness questions at post test.

### **Measures**

#### *Participant Responsiveness*

Participant responsiveness was assessed at post test on the last day of program delivery through participant self report. Eight items in total, were used to capture dimensions of participant responsiveness for teen pregnancy programs. The first six items that measured participants' interest in sessions (*interest*), clarity of material as perceived by

the participant (*material*), usefulness of discussions as perceived by the participant (*discuss*), respect of the participant in the classroom (*respect*), bullying of the participant in the program (*bully\_you*), and participant ability to ask questions in the program (*ask*). The next two items assessed group environment, specifically participant perception of bullying of other youth due to sexual orientation (*otherbully\_orient*) and participant perception of bullying of other youth due to race/ ethnic background (*otherbully\_race*). Response categories were in the form of a five point Likert scale: 5= all of the time, 4= most of the time, 3= some of the time, 2= a little of the time, and 1= none of the time.

### **Data Analysis**

Psychometric testing of participant responsiveness measure involved the following steps:

1) CFA was conducted on a random split-half sample of the data to examine the factor structure, 2) A CFA was conducted on the remaining sample to validate the refined factor structure, 3) A multi-group CFA was used to test measurement and structural invariance of the latent constructs between programs. All data analysis were completed using MPlus7.3.<sup>19</sup> To conduct a CFA, complete data is required<sup>20</sup> therefore, Full Information Maximum Likelihood (FIML) was used in the Mplus 7.3 software program to deal with missing data. More specifically, to adjust for possible multivariate non-normality, the robust estimator option MLR was used for model estimation.<sup>19,21</sup>

### *Confirmatory Factor Analysis*

Based on previous research, the initial confirmatory factor analysis model included two latent constructs: 1) individual level indicators of participant responsiveness such as individual's interest in the session and 2) individual perception of group environment.

**Figure 1** depicts a path diagram of the final CFA measurement model. We will primarily rely on confirmatory factor analysis (CFA) with means structures to evaluate the measurement properties of the responsiveness scale. CFA is an analytic technique that allows for the examination of observed and latent variables within a single group or across multiple groups.<sup>20</sup>

To develop and validate the proposed structure, the sample was randomly divided in half so that a CFA could be completed on the first half of the sample, and a subsequent CFA could be completed on the second half of the sample. For the CFA on the first half of the sample, the hypothesis was tested. The following fit statistics were used to determine appropriate fit: a) Root-Mean-Square Error of Approximation (RMSEA)<sup>22</sup>, (b) the Tucker Lewis Index (TLI)<sup>23</sup>, and the (c) Comparative Fit Index (CFI)<sup>24</sup>. Acceptable RMSEA values are less than or equal to .08<sup>20</sup>, while values greater than .09 are considered acceptable for the NNFI, and the CFI.<sup>20,25,26</sup> TFI and CFI values above .90 demonstrated acceptable model fit and values above .95 demonstrated good model fit.<sup>23</sup> Based on model fit, items were adjusted or removed in the CFA to produce a better model fit. Once appropriate model fit was established, a second confirmatory factor analysis with a refined model was conducted on the second half of the sample to serve as a validity test.

#### *Multiple group confirmatory factor analysis*

A multiple group confirmatory factor analysis was conducted to determine how the factor structure held across different evidence based models.<sup>27</sup> For instance, the primary goal of

this technique will be to establish that the factor structure does not change as a function of the evidence based model so that comparisons of means of the construct across models are meaningful and true. This analysis was completed in three steps: 1) configural model testing and 2) testing the configural model with a less constricted model (loading invariance) and 3) to a more constricted model (intercept invariance). In the configural model, all factor means are fixed to zero, scale factors are fixed to one, and thresholds and loadings are unconstrained. For loading measurement invariance, factor loadings are set equal and tested. For intercept invariance, in addition, intercepts are set equal and tested. To assess significance of the comparison between models, the following statistics were observed: a) RMSEA value of the nested model is within the confidence interval range of the comparison model <sup>28</sup> and b) the difference in CFI between the nested model and the comparison model is no greater than .01.<sup>29</sup>

#### *Omega Estimation for Scale Reliability*

The scale reliability was assessed using Coefficient Omega ( $\omega$ ) with a 95% Bias-Corrected Bootstrap confidence interval.<sup>30,31</sup> The omega estimation can be interpreted the same as Cronbach's alpha, however it is a more accurate estimate because it does not assume all items carry equal loadings and variances, and can be used with hierarchical data.<sup>31,32</sup>

#### *Latent Mean Differences Across Programs*

Once measurement invariance was established, a test of equivalence of latent variable means among programs was examined. An effects coding method <sup>33</sup> was used in Mplus



to identify estimate the model and latent means. Then, the Satorra-Bentler Scaled Chi-Squared Difference Test ( $\chi^2_{SB}$ ) was used to determine if the means differ.<sup>34</sup>

## RESULTS

### Study Sample

A total of 2,242 participants across all seven implementing programs was used for the analyses. **Table 1** demonstrates participant demographics, sexual behavior at baseline (pre test), and response frequencies of participant responsiveness items, stratified by program. Data for **Table1** was obtained from 2,242 participants across all seven implementing programs. There were significant differences in age, gender, ethnicity, race, baseline sexual behavior, and SES across programs. There were significant differences in each participant responsiveness measure across programs. Frequencies of participant responsiveness items are skewed towards the positive. The maximum full information maximum likelihood was used to handle missingness in Mplus. The greatest number of missing cases for any item was less than 5% of the sample; no further action such as imputation was taken as the loss of power and bias in deletion of cases less than 5% is considered negligible<sup>35</sup>

**Table 1: Participant Demographics, Sexual Behavior at Baseline, and Participant Responsiveness Frequencies of Respondents by Evidence Based Programs among Adolescents in New Jersey (N=2,242)**

	<i>Be Proud! Be Responsible!</i> n=274	<i>Reducin g the Risk</i> n=456	<i>Making Proud Choices 1</i> n=82	<i>Making Proud Choices 2</i> n=685	<i>SIHLE</i> n=114	<i>Teen Health Project</i> n=399	<i>Teen Outrea ch Progra m</i> n=144	All Program s n=2,242	P value
DEMOGRAPHICS									
Age									
Mean (SD)	16.4 (2.19)	15.68 (.90)	16.87 (1.10)	14.63 (2.27)	16.98 (1.51)	15.65 (1.64)	14.65 (1.66)	15.45 (1.96)	.00
Gender									
Male (%)	58.76	45.83	100	48.03	0	47.87	32.33	46.70	.00
Female (%)	40.15	52.85	0	51.24	99.12	51.38	67.24	52.45	
Ethnicity									
Hispanic (%)	48.91	31.36	0	40.15	17.54	62.66	52.59	41.96	.00
Race									
American Indian (%)	5.11	6.58	2.44	5.99	2.63	7.27	3.88	5.71	.00
Asian (%)	0.36	5.70	0	5.84	0	1.50	1.29	3.39	
African American (%)	45.62	62.06	97.56	55.33	87.72	30.08	47.84	53.43	
Pacific Islander (%)	1.82	4.31	0	3.36	0	2.01	4.61	2.99	
White (%)	29.93	6.36	2.44	15.04	2.63	24.81	14.22	15.66	
Maternal Education									
Less than a high school degree/GED	24.09	13.16	23.17	13.87	24.56	32.58	20.69	19.89	.00
High school degree/GED	31.75	39.69	45.12	25.99	50	32.83	29.74	33.01	
Greater than highschool degree	29.93	37.72	25.99	44.53	23.68	27.07	28.45	34.97	
BASELINE SEXUAL BEHAVIORS									
Ever Had Sex									
Yes	57.30	35.31	70.73	22.63	60.53	33.83	17.67	34.61	.00
No	32.12	58.33	24.39	64.09	35.96	62.41	70.69	56.51	
PARTICIPANT RESPONSIVENESS									
Did you feel interested in program sessions and classes?									
All of the time	50.00	53.51	52.44	38.41	67.54	48.87	47.19	47.19	.00
Most of the time	32.48	28.95	30.49	32.03	24.56	33.08	32.07	32.07	
Some of the time	12.77	10.96	10.98	18.99	7.89	11.28	13.92	13.92	

A little of the time	1.09	3.73	1.22	5.65	0	2.26	3.39	3.39	
None of the time	3.65	2.63	4.88	3.77	0	4.01	3.12	3.12	
Did you feel the material presented was clear?									
All of the time	63.50	65.35	64.63	59.56	70.18	63.91	47.47	61.46	.00
Most of the time	25.55	24.12	25.61	27.88	23.68	23.56	34.05	26.40	
Some of the time	8.39	5.70	3.66	8.76	3.51	5.01	13.79	7.49	
A little of the time	.73	2.41	4.88	1.17	.88	2.01	2.59	1.78	
None of the time	.73	1.32	0	1.46	0	2.01	1.29	1.29	
Did discussions or activities help you to learn program lessons?									
All of the time	61.68	71.05	64.63	61.46	77.19	63.16	49.14	63.38	.00
Most of the time	28.83	18.20	20.73	25.40	19.30	23.81	33.62	24.44	
Some of the time	7.30	6.8	9.76	9.49	3.51	8.02	12.93	8.47	
A little of the time	.73	1.54	2.44	1.61	0	1.75	.86	1.38	
None of the time	.36	1.54	2.44	1.61	0	2.51	2.59	1.65	
Did you feel respected as a person?									
All of the time	74.09	78.07	81.71	73.43	82.46	73.18	56.90	73.46	.00
Most of the time	17.52	13.60	10.98	16.06	15.79	15.04	25.86	16.37	
Some of the time	5.84	5.04	4.88	5.55	1.75	4.76	11.21	5.71	
A little of the time	0.73	0.88	1.22	2.19	0.00	1.25	2.16	1.43	
None of the time	0.73	1.32	0.00	1.90	0.00	1.75	2.16	1.47	
Were you picked on, teased, or bullied in this program?									
All of the time	7.30	9.21	3.66	5.51	10.53	10.53	8.62	7.789	.00
Most of the time	2.19	4.82	4.88	2.61	4.39	3.51	4.74	3.57	
Some of the time	3.28	3.29	2.44	4.49	2.63	4.01	5.60	3.97	
A little of the time	4.38	4.17	4.88	2.46	1.75	3.26	7.33	3.75	
None of the time	81.75	76.97	82.93	83.91	77.19	77.44	70.69	79.53	
Did you have a chance to ask questions about topics or issues that came up in the program?									
All of the time	60.58	63.01	62.20	56.09	57.50	57.75	46.86	57.21	.00
Most of the time	21.53	18.28	20.73	19.42	19.17	19.25	23.01	19.67	
Some of the time	13.50	10.32	14.63	12.32	4.17	7.75	17.57	11.36	
A little of the time	0.68	2.80	1.22	6.09	1.67	5.50	3.77	3.98	

None of the time	2.40	3.01	1.22	4.64	11.67	6.00	2.93	4.33	
Were youth in this program picked on, teased, or bullied because people thought they were lesbian, gay, bisexual, or transgender?									
All of the time	0.73	3.95	3.66	3.07	1.75	4.01	4.31	3.121	.00
Most of the time	1.09	3.73	1.22	2.04	4.39	4.51	3.88	2.99	
Some of the time	5.11	5.70	1.22	3.65	0.00	4.76	7.76	4.59	
A little of the time	2.92	6.14	2.44	4.38	0.00	4.01	7.33	4.50	
None of the time	88.69	76.97	90.24	86.72	89.47	80.45	75.43	82.96	
Were youth in this program picked on, teased, or bullied because of their race or ethnic background?									
All of the time	1.09	3.29	1.22	1.90	2.63	4.01	4.31	2.72	.00
Most of the time	1.09	1.97	2.44	2.04	1.75	2.26	2.16	1.96	
Some of the time	4.38	4.39	0.00	4.53	0.88	3.26	7.76	4.24	
A little of the time	2.55	3.95	4.88	5.40	0.00	3.26	6.90	4.24	
None of the time	87.96	82.68	90.24	85.26	88.60	76.94	77.59	83.14	

### Confirmatory Factor Analysis

Applicable items were reverse coded so that higher participant responsiveness scores indicated higher participant responsiveness to the program. In the first half of the sample, a CFA was conducted with *interest*, *material*, *discuss*, *respect*, *bully\_you*, *ask* items hypothesized to load onto one latent variable (individual level participant responsiveness), and *otherbully\_orient* and *otherbully\_race* items to load onto a second latent variable (group level participant responsiveness). Loadings and subsequent model fit statistics are indicated in **Table 2**. *Bully\_you* loaded poorly, with a factor loading of .040, on the first latent variable. *Bully\_you* was further tested to map onto the second latent variable, given that they all measured bullying and loadings and fit statistics were examined (**Table 2**). The fit statistics for the model excluding including *bully\_you* onto the second variable were superb to the model with *bully\_you* mapped onto the first

variable and demonstrated good model fit (RMSEA = .045, CFI = 0.974, TFI= 0.962 versus RMSEA = .099, TFI = 0.818, CFI = 0.870).

**Table 2: Confirmatory Factor Analyses Factor Loadings on participant responsiveness items on first half of sample n=1,122**

Participant Responsiveness	Initial Model n=1,122		Refined Model Program 5 on LV2 n=1,122	
Item Loadings	LV 1	LV2	LV1	LV2
interest	.631		.631	
material	.799		.799	
discuss	.817		.817	
respect	.682		.682	
bully_you	<b>.040</b>			.494
ask	.480		.480	
otherbully_orient		.870		.906
otherbully_race		.926		.890
RMSEA (CI)	.099 (.088-.110)		.045 (.033-.058)	
CFI	.870		.974	
TFI	.818		.962	

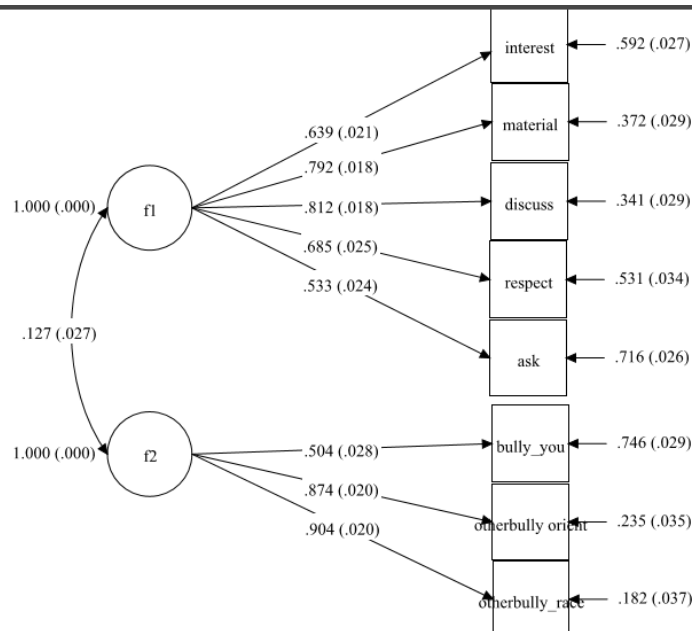
A confirmatory factor analysis was conducted on the second half of the sample to serve as a validity test of the refined model (**Table 3**). Fit statistics demonstrated good model fit (RMSEA = .044, TLI = 0.961, CFI = 0.974

**Table 3: Confirmatory Factor Analysis Fit Statistics for each half sample and full sample**

Model	$\chi^2$	<i>df</i>	RMSEA	90% CI	CFI	TLI
First Half Sample Refined Model n=1,122	62.403	19	.045	.033-.058	0.974	0.962
Second Half Sample Validity Test n=1,120	59.314	19	.044	.031-.056	0.974	0.961
Full Sample N=2,242	108.367	19	.046	.038-.054	0.972	0.959

The loadings and fit statistics for the confirmatory factor analysis model on the full sample is indicated in **Table 3**. Fit statistics showed a good fit with the full sample with RMSEA below .05 and TLI and CFI above .95 (RMSEA = .046, TLI = 0.959, CFI = 0.972). See **Figure 1** for final loadings and correlation between latent variables. Completely standardized (stdXY) estimates are presented in **Figure 1**.

**Figure 1: Final Loadings and correlation for Confirmatory Factor Analysis**



### Multigroup confirmatory factor analysis

The final refined model structure with *interest*, *material*, *discuss*, *respect*, and *ask* loading onto one latent variable (participant responsiveness) and *bully\_you*, *otherbully\_orient*, and *otherbully\_race* loading onto another latent variable (group environment) was tested across all programs. A series of three tests were implemented to determine measurement invariance. As shown in **Table 4**, The initial configural test demonstrated acceptable fit (RMSEA = .054, TLI = 0.939, CFI = 0.957). We set the loadings equal to each other to determine weak measurement invariance and found no significant changes in fit from the configural model (CFI was less than .01 difference and RMSEA was within the confidence interval (.044-.064). Then, we equated the intercepts to determine strong measurement invariance and found no significant changes in RMSEA (.051) from the weak invariant model (within confidence interval .036-.054); however there was a .02

difference in CFI, as opposed to .01 difference. Given an acceptable RMSEA, and close values in CFI, these statistics demonstrate that the resulting factor structure is invariant across programs.

**Table 4: Fit Indices for the Nested Sequence in the Multiple Group Confirmatory Factor Analysis**

Model	$\chi^2$	df	RMSEA	90% CI	CFI	TLI
Configural Invariance	264.291	136	.054	.044-.064	0.957	0.939
Loading Invariance	288.992	175	.045	.036-.054	0.962	0.958
Intercept Invariance	386.216	211	.051	.043-.059	0.942	0.946

### Reliability Estimation

Reliability was measured using Coefficient Omega ( $\omega$ ) with a 95% Bias-Corrected Bootstrap (BC) confidence interval (McDonald, 1999; Raykov, 1997). The reliability for the LV1 is .808 (.788-.826) and the reliability for LV2 is .773 (.741-.798).

### Estimation of latent mean differences across programs

The Santora Bentler chi square difference test indicated that there were significant differences in latent means across programs ( $\Delta\chi^2 = 59.96$ ,  $Cd = 1.35435$ ,  $p < .01$ ). **Table 5** indicates the latent means by program. Differences in latent variable 1 mean ranged from .02-.39. Cohen's d was used to determine effect size. Cohen's d for participant responsiveness latent variable ranged from .02-.80, with a mean of .244. The largest effect size of .80 was between Teen Outreach Program and Sihle program. Differences in



group environment latent variable ranged from .01-.28. Cohen's d for latent variable 2 ranged from .03- .40, with a mean of .183.

**Table 5: Latent Means Estimation Across Evidence Based Programs**

Latent Means Estimate (S.E.)	<i>Be Proud! Be Responsible!</i>	<i>Reducing the Risk</i>	<i>Making Proud Choices1</i>	<i>Making Proud Choices2</i>	<i>Sihle</i>	<i>Teen Health Project</i>	<i>Teen Outreach Program</i>
f1	4.447 (.036)	4.475 (.032)	4.486 (.073)	4.351 (.026)	4.633 (.042)	4.403 (.038)	4.244 (.046)
f2	4.730 (.036)	4.540 (.045)	4.716 (.083)	4.643 (.028)	4.732 (.068)	4.509 (.049)	4.456 (.061)

## DISCUSSION

In this paper, we assessed the psychometric properties of state-wide survey questions capturing participant responsiveness among 2,242 adolescents receiving six different evidence based sexual reproductive health programs. We first assessed the underlying factor structure and properties of participant responsiveness questions with one half of the sample and then validated this factor structure with the second half of the sample. We also determined if this factor structure held across seven different programs. Lastly, we determined latent mean differences between the programs. Eight items or questions mapped onto two different latent variables. In the refined model for the full sample, all items had loadings greater than 0.50, with most items loading greater than 0.60. When *bully\_you* was mapped onto the latent variable measuring individual participant responsiveness, *bully\_you* had a low loading of 0.040. This item addressed personal teasing and bullying- an indicator of environment. *Otherbully\_orient* and *otherbully\_race* also assess teasing and bullying- as related to ethnicity or sexual orientation. These three items held together, and the loading of *bully\_you* was greater than 0.40 when mapped onto this latent variable. This latent variable was related to

classroom or peer environment, particularly bullying or discrimination between program participants. The remaining items correspond to individual participant responsiveness measures that relate to program liking (interest, skill usefulness, clarity) as well as feeling respected and being able to ask questions. All of these measures relate to the facilitator or program protocol, measures that are specific to program implementation delivery. This finding corresponds with Schoefelder in that peer and group environment participant responsiveness differs from individual participant responsiveness <sup>14</sup>.

The final model fit statistics demonstrate that the final refined factor structure is both reliable and valid among adolescents, with a mean age of 15.46, demographic distribution of 41.96% Hispanic and 53.45% African American with some level of sexual risk, with roughly 1/3 having had sex. Fit statistics also show that this factor structure is invariant across programs. This is especially important to note because the seven programs differ significantly in composition of participant age, gender, baseline sex, ethnicity, and race.

Participant responsiveness latent means were generally high, ranging from 4.244-4.633 for F1, and 4.456-4.732 for latent variable 2. High participant responsiveness to sexual health curriculum for adolescents are echoed in other studies as well. <sup>36,37</sup> Results indicated significant differences in latent means across programs. Significant differences were particularly apparent in latent variable 1 measuring individual program liking. Cohen's effect size ranged from .02-.80. It is important to note that overall the mean effect size was .24, which is considered small. Regarding latent variable 2, the range of Cohen's d was much smaller, indicating much less of a difference between sites with peer

environment experiences of discrimination. Given that measurement invariance has been established across all programs, we can say that the differences in participant responsiveness between programs are true differences in participant responsiveness. Even so, it is important to note the positive skewness towards high scores might limit the ability of this measure to serve as a mediator of fidelity and program outcomes or from pre to post test outcomes. The lack of variability in this measure may not reflect the lack of variability in sexual reproductive health program outcome measures, which has implications for how we think about this construct conceptually.

### **Limitations and Strengths**

Participant responsiveness measures were positively skewed; however, adjustments were made in the analyses to account for the skew. In addition, the participant responsiveness measures used are based on self report. Strengths of the manuscript include the large sample size ( $n = 2,242$ ), which enabled us to conduct a validity test. In addition, another strength of the manuscript is that it contributes to the psychometric testing of implementation measures, and specifically addresses this for the adolescent population of mixed ethnicity and race.

### **Conclusion**

In conclusion, this refined scale was tested as a valid and reliable scale to assess participant responsiveness for urban adolescents, ages 10-19, of mixed race and gender and has implications for widespread use among a variety of sexual reproductive health

programs. Given the non specificity of question items to sexual and reproductive health, this scale also has implications for use in measuring participant responsiveness to public health programs outside of sexual and reproductive health that employ the use of facilitators and an interactive pedagogy to target behavior change in adolescents.

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## **5. “YOU CAN GET MORE OUT OF A KID IF YOU’RE ABLE TO STRAY A LITTLE BIT”: PROGRAM IMPLEMENTER PERSPECTIVES ON STRATEGIES AND CHALLENGES IN THE REPLICATION OF EVIDENCE-BASED SEXUAL REPRODUCTIVE HEALTH PROGRAMS WITH ADOLESCENTS**

### **INTRODUCTION**

Since 2009, the Family Youth and Services Bureau (FYSB) and the Office of Adolescent Health (OAH) have provided substantial funding for the development, testing, adoption, and replication of evidence based programs in the field of sexual and reproductive health (SRH), representing the nation’s largest coordinated effort in teen pregnancy prevention.<sup>1–3</sup> Implementation is posited as a key contributor to replication success.<sup>4–10</sup> Implementation is defined as “a specified set of activities designed to put into practice an activity or program of known dimensions.”<sup>11</sup> Literature shows there are multilevel upstream contextual factors that activate program implementation.<sup>6,11–17</sup> Given the relationship between implementation and program outcomes, it is important to understand the contextual factors that affect translation of these programs in different settings and populations from the initial efficacy study. Chen<sup>15</sup> includes among these multiple levels factors such as program participant factors (i.e. age or baseline sex behavior<sup>13</sup>), implementer factors (i.e. implementer experience, implementer beliefs toward the intervention<sup>18,19</sup>); program manual factors (i.e. quality of materials, adaptability of the program<sup>6,14</sup>); implementing organization factors (i.e. priorities of the organization)<sup>18,20</sup>; and community factors (i.e. partner site support, setting of delivery).<sup>6,19,21</sup> Despite general literature on strategies and challenges to implementation of programs, few studies take into account contextual factors from the perspective of

implementers of sexual and reproductive health EBPs themselves, and with an adolescent population.<sup>6,22</sup>

Given the unique needs and developmental processes that take place during adolescence (ages 10-19), exploring factors related to the implementation of sexual and reproductive health adolescent programs may be particularly important. Adolescent females experience the highest rates of many sexually transmitted infections such as chlamydia and gonorrhea compared to other age groups in the United States. Adolescence is also a period marked with remarkable growth biologically and in the development of attitudes towards sex. It is a time period where the influence of peer and parental norms may be particularly salient.<sup>23</sup> Among adolescents with a lack of parental support or violent home environments, there may be distinct challenges to the implementation of programs. Additionally, mechanisms by which adolescents communicate today (online and social media)<sup>24</sup> may differ from settings in which programs were originally tested.

Replication studies differ from other studies in that settings, program implementers, and the time period may be different from the initial testing. Replication studies of evidence based programs often strive to maintain fidelity (also referred to as adherence) of the original program and the developers may have particular design elements that they consider critical to the program. A tension may rise in the replication of evidence based programs, however, because given the differences in settings of the replication study compared to the original setting, program staff including facilitators may need to make



adaptations. The Department of Health and Human Services defined adaptations for NJPREP as “making changes to an Evidence-Based Program (EBP) so that it is more suitable for a particular population or an organization’s setting or program structure without compromising or deleting its core components and categorized adaptations into ‘green’, ‘red’, and ‘yellow light’ adaptations.”<sup>25,26</sup> Adaptations may be made to the content delivered, the way in which the content was delivered, or in the logistics of delivery. This merits further exploration into the tension between fidelity and adaptation.

This study used qualitative methods (i.e. in depth interviews) to explore implementer (i.e. program facilitators and managers) opinions on EBPs, adherence and adaptations, and successes and challenges to implementation of SRH EBPs.

## **METHODS**

The present qualitative study was nested within a parent mixed-methods evaluation study and explored implementation experiences of program implementers through in-depth interviews. In the parent evaluation study, the Johns Hopkins Center for Child and Community Health Research evaluated six evidence-based sexual reproductive health programs implemented as a part of the Personal Responsibility Education Program (PREP) with the New Jersey Department of Health (NJDOH), Family Health Services Division from 2011-2015. The federal initiative drew on the list of evidence-based sexual reproductive health programs that were deemed ready for widespread replication by the OAH.<sup>27</sup> The NJ PREP program funded six organizations which selected six evidence-based programs: *Making Proud Choices*, *Teen Health Project*, *Teen Outreach*

*Program, Reducing the Risk, Be Proud! Be Responsible!* and *Sisters Informing Healing Living Empowering*. Identified programs included information on abstinence and contraception, as well as healthy relationships, attitudes and values about adolescent growth, financial literacy, parent-child communication and job success. A requirement of funding was that at least half of program participants resided in communities of high teen pregnancy and STI prevalence. In total, the programs were implemented among 2,698 primarily African American and Hispanic adolescents, ages 10-19 years, in school and community-based settings. The Johns Hopkins School of Medicine Institutional Review Board reviewed and approved all study protocols.

### **Data Collection**

The study was conducted from May 2015-July 2015, after each program had been implemented for at least two years. All program implementers (n=20) currently employed by the six organizations and actively serving as either facilitator or program manager of the evidence-based program were eligible for the study. Study participants were screened for eligibility and provided written consent prior to the interview.

Individual interviews were conducted via telephone or Skype and were conducted by one female interviewer (JP). After pilot testing for comprehension and clarity, the interviewer used a semi-structured interview guide to facilitate discussion on the following: 1) implementer background and experiences, 2) implementer perspectives on evidence-based programs, 3) adaptations, and 4) opportunities and challenges to implementation. The interviews lasted between 45-60 minutes and were recorded.

## **Data Analysis**

All interviews were subsequently transcribed, reviewed for completeness, and de-identified before entry into Atlas.ti qualitative software.<sup>28</sup> Interview transcripts were coded and analyzed for emerging themes by two trained qualitative study team members through an iterative process of co-developing a codebook, coding transcripts independently, reconciling differences through discussion, and developing themes.<sup>29,30</sup>

## **RESULTS**

### **Program implementer characteristics**

Eighteen of the 20 program implementers completed individual interviews. Of these, twelve were primarily facilitators; three served as both facilitators and program managers; and three worked solely as program managers. Implementers were between 23 and 63 years old. Seventeen implementers were female and one was male. Sixteen implementers had at least a bachelor's degree; and of these, seven held a graduate degree. Eleven implementers were white, four were black, two were mixed race, and one was South Asian. This was the first experience implementing an evidence-based program for 66% (12/18) and 61% (11/18) had extensive experience working with youth, ranging from 4 to 25 years of experience. Additionally, 66% (12/18) of the implementers had longstanding relationships with their implementing organizations, ranging from 7-13 years.

## Contextual factors that affect implementation of SRH EBPs

**Table 1** represents emerging themes regarding strategies and challenges to effective implementation, from the perspectives of program implementers, and organized into four levels: curriculum, implementer-participant relationship, partner relationships, and factors specific to the replication context with which EBPs are delivered.

**Table 1: Emerging themes regarding factors to effective implementation of SRH EBPs among adolescents organized by level and type of factor (i.e. strategy or challenge)**

Level	Strategies to implementation --Relationship building--	Challenges to implementation --Tension with fidelity--
<b>Curriculum</b>	Holistic curriculum components (i.e. healthy relationships) Setting goals	Outdated program components Heteronormative nature SRH knowledge assumptions Need for flexibility
<b>Implementer-Participant Relationship</b>	Developing a bond between program implementer and participant	Students have many questions- not enough time to address them
<b>Community partner site</b>	Strong relationships with community partner sites	Scheduling difficulties with partner sites
<b>Replication/evaluation-specific factors</b>	Making adaptations and being flexible	Need to adhere to curriculum Reporting of adaptation data

### **Challenges to implementation:**

The factors that challenge implementation relate to a central theme of tension with fidelity and are presented here by level: curriculum, implementer-participant relationship, partner site, and replication specific factors.

### ***Curriculum***

Program components are often outdated: Program implementers from at least half of the programs felt their programs were outdated with culturally irrelevant videos and role-

plays. Many of these programs were developed decades ago and program implementers reported they did not take into account how adolescents currently communicate or interact (i.e. texting and social media). Additionally, the program assumed heterosexual relationships:

*When it does really bother me it's things like when a sign clearly says up there like 'Real sex is vaginal sex.' ... I want to be able to incorporate more of the gender equality and ...orientation equality, ... but you got to do what you got to do, right?*

These concerns were especially frustrating if the implementing organization's specialty is focused on sexual reproductive health. A program implementer said, "*you know, we're a premiere educator of sexual reproductive health and so when you're tied to a curricula that's kind of outdated ...it's limiting.*"

Need for flexibility in the curriculum: In five out of the six programs, implementers expressed the need for flexibility in the program. Some program implementers wanted more time for relationship and rapport building, others wanted more time to address questions students may have about sex or topics not in the program, others wanted the flexibility to debrief after a stressful event the participants experienced (i.e. encounters with police or neighborhood shootings), and still others saw the need for the flexibility to tailor the program to participant age.

*Say if it was, okay, on this day you can choose between two different lessons. Like at least that gives the facilitator some sort of choice to what they think that their participants or their students would work best for their participants, as opposed to a one size fits all.*

One program was the exception in that it did allow implementers choice, and that was greatly appreciated:

*I love its flexibility in terms of the lessons and being able to pick different lessons for the scaffolding that goes on for different levels and different groups, and that's awesome, because there's not a set order of lessons. It's really up to you to define which lessons you're going to use and when, so that I really like.*

Programs assume knowledge of anatomy that is often lacking:

Program implementers noted that while program participants had heard HIV/STD messages, they lacked knowledge of basic reproductive biology and anatomy.

Implementers felt that including such information would help participants contextualize and better understand the material. A staff member reflected that evidence-based programs wrongly assume that anatomy is covered in school:

*Unfortunately, our curriculum makes a lot of assumptions about our students. Because even though it says it's geared towards a certain age, just to be quite honest, a lot of our schools don't do what they're supposed to do in terms of sexual health education, so I've had high schoolers ask me [questions that indicate] ... they don't even know like basic anatomy. Or they don't know reproduction. So I would build in more time to kind of go over the basics.*

### ***Implementer-Facilitator Relationship***

Sufficient time for adolescent questions is often lacking: All program implementers noted that adolescents had many questions during their sessions. Participants reported that the program may serve as one of the few and first times adolescents have the opportunity to discuss sex with a supportive adult; so, adolescents capitalize on this opportunity.

*Teaching a curriculum is one thing to anybody, but then actually going out in the field to these I feel like more at-risk sites or any school depending on the community, this is reality. We're going to come across questions that we need to answer. We can't just squash them and say 'Let's move on.' So, I feel that even if the funder or whoever comes out and actually I think spends a little bit more time with what we're actually dealing with, I think that would be helpful so they can see that it's not easy to stick to the curriculum.*

Another noted that failure to address participant needs and questions could impact retention and engagement:

*[There] is no way, no, no, no way that you can actually get through this curriculum in one hour based on the design. Because it doesn't allow for any questions, it doesn't allow for a conversation, it doesn't allow for kids to go, "but wait a minute, wait", you know? ... kids feel like... they have no control over the conversation and so, that impacts retention.*

Additionally, the lack of time to complete the curriculum as designed created an internal struggle within program implementers as they are left to choose between completing the program and answering participant questions.

*Because I felt so pressured to complete the curriculum in the amount of time, you know, I could not engage students the way I really wanted to, because I couldn't answer the questions that they wanted to, you know, me to answer... I just basically had to sacrifice engagement to fulfill my contractual agreement to deliver this curriculum.*

### ***Community Partner Site***

Scheduling changes were common to accommodate community partner needs: One of the challenges implementers experienced was scheduling constraints with their community partners including: unannounced field trips, winter weather, and state-mandated student testing. These were greater issues at schools than community-based sites. Additionally, schools have other priorities beyond sex education, which limit the amount of time they can allocate to evidence-based programs.

*I have to admit even though I like the model, I don't think it's realistic for high schools, and it's not because the high schools didn't allow us in, but it's just so many lessons, and because we're not a priority in these high schools; we're the first thing that's going to be bumped off.*

### ***Replication-specific factors***

The need to adhere to the curriculum: The need to maintain fidelity limited autonomy of program implementers and caused frustration.

*It's important that you have to follow the fidelity... I know how important it is... I feel like it becomes frustrating in any single moment where you feel like you can get more out of a kid if you're able to stray a little bit.*

*Because of fidelity, I have very little latitude into how I change my presentation or what language I use. It was always kind of impressed upon at our team meetings was that we had to follow fidelity ... and that was probably the biggest challenge because it didn't seem to consider the audience and the kind of questions that they may have and just their lack of maturity and engagement.*

*I think as someone who is creative, like it can feel a little bit stifling. But again, I just know that's the name of the game. I know that's what we have to do.*

An example of the dilemma a program implementer faced follows. He/she was presented with a choice of engaging the students and responding to their needs or making an adaptation that was not considered a “green light” adaptation.

*One other activity that really bombed every time I did it...when we had to do condom demonstrations on how to put a condom on correctly, in almost every class that I taught, none of the boys wanted to touch the penis model, they just didn't want to touch it, they didn't want to touch it and the curriculum is clear on, based on the evidence, they had to demonstrate putting on the condom... And I wasn't going to force boys to do something that they didn't want to do, so either I did it for the boys and demonstrated for them to observe me or I asked for volunteers to do it.*

Reporting of adaptation data: Implementers were required to report adaptation data as part of a larger evaluation project. Some program implementers felt reticent in recording adaptations or making any changes (minor or major) to the program; and, in some cases this resulted in increased adherence to the prescribed curriculum:

*And the rule of thumb for us was anytime anything that was not exactly as written, you're checking that middle box (completed with changes). And we had an actual staff meeting, because it was hard, I think, for everyone to check that box. You don't want to feel like you're not doing what you're supposed to be doing, but are we doing exactly as written? No.*



*There's no way that we can fill out a fidelity form for every single session that we do. It would be insanity. So I just decided 'Okay, I'm just going to have to stick to the curriculum, and hopefully it will work'.*

One factor fueling this tension was the lack of clarity on how to define an adaptation and negative connotations ascribed to adaptations:

*I feel like we get so many bombarding-- conflicting messages about what an adaption is and what is not an adaption ... I have the definition where any single thing not in this book is an adaption, and then I have my program developer coming out and being like, 'Oh, well let's move this around, and this is okay they're still getting the content.' So it's not an adaption.*

### **Strategies to implementation:**

The factors that facilitate implementation relate to a central theme of building relationships and are presented here by level: curriculum, implementer-participant relationship, partner site, and replication specific factors.

### ***Curriculum***

Not just STI/HIV knowledge: While program implementers recognized the necessity of core program components such as STI/HIV knowledge, implementers from all programs highlighted other components, such as healthy relationships and values and goals, as indispensable for sexual risk reduction:

*The components of it [the intervention] that excite me are the components around what is healthy and unhealthy relationship, how do I effectively communicate ... Yes, we need to provide options around STDs and HIV...but I don't think that the emphasis needs to be on ... STD, HIV, and condom demonstration... [the] emphasis needs to be on other skills that young people can develop... and I think that is sorely needed.*

Program implementers noted this as a particular need with adolescent girls, as they navigate their romantic relationships and begin to grapple with questions of love and

issues of abuse. Implementers delivering curriculums that did not address healthy relationships noted in particular the need:

*We ask them 'So why aren't people using condoms, or why aren't you using condoms?' because they come out and tell us that 'I'm not using them because my boyfriend doesn't want me to, because then he thinks I'm dirty or stuff like that or I'm cheating on him,' and I said 'That's where it comes down to talking about a healthy relationship and healthy communication between you and your partner.'*

*I wish the program had more-- maybe talk about, a little bit about sexual abuse; at least maybe one lesson would be on sexual abuse. A lot of students maybe don't know that they have been abused; and some students, one student came up to me and said certain things, that I guess wasn't sure that she was sexually abused or not. And you know, I can't do anything about it, just you know, make sure that I referred her to the right person, which I did.*

Another important component outside of HIV/STD messages includes adolescents recognizing the implementing organization as a source of support for their sexual reproductive health needs:

*"Probably even more importantly not that they remember all of the details of what they learned, but that they know that there are organizations like [X] ... and other resources that are available to them at whatever point in their lives they need those resources. So I think that's always a huge component that might not always get evaluated but that nonetheless is probably one of the most impactful pieces of delivering any kind of sexual health information*

Related to relationships are values and goals:

*What I really loved in the first session—and there wasn't enough of it—was basically talking about setting goals and having students talk about when they were five years old, where they wanted to be and then when they were ten years old, where they wanted to be and then five years ago, 'Where did you want to be?' ... I think really helped boys think about being responsible.*

### ***Facilitator- Implementer Relationship***

Strong bonds between facilitator and program participants matter: Program implementers emphasized the importance of forming relationships with program participants in order to set the stage for delivery of the program:

*You can't just go in and have an agenda and then, if a student asks a question ... [he or she] obviously is in need at that moment, just brush them off 'cause... I think it sets the tone for your group, and how they view you.*

This is especially important because, as program implementers note, “a lot of teens don’t really have a whole lot of people that they really can trust.” The frequency of meetings with participants helped implementers develop closer relationships with program participants.

*We get to work with the same kids over and over again. They really like us, and the fact that they like us helps them really get into the content a little bit more. I found that they really want to talk about this stuff and they want to make it about them... Usually we just do a one shot program and that's it, so this has been a really unique experience for me as far as it being numerous times I get to see the same people. So that piece of it has been really, really wonderful for me.”*

One program implementer noted that the facilitator-participant relationship is so central that they were not sure whether to attribute success to the program or to the facilitator:

*I think it's overall been positive and I don't know if that's because...of the curriculum itself or because of the facilitators... they [the adolescents] don't want us to leave.*

### ***Community Partner Site***

Strong links with community partners matter: Across the board, program implementers noted one of the most impactful implementation strategies was fostering a relationship with community partners:

*I think equally as important is having great staff and having great partners because you really need to put a lot of trust in the fact that they're going to hold up their end of the bargain because frankly, without them you don't have a program.*

Prior existing relationships or work with community partners aided the implementation of new evidence-based programs, in settings that otherwise might not have been receptive (i.e. conservative school boards). When asked to provide specific strategies on how to foster relationships with community partners, program implementers reported the following: having a memorandum of understanding, meetings before the program starts to inform all stakeholders of the program, marketing the program as beneficial to the school (i.e. improve academic behavior, fulfill a health education requirement), connecting after implementation sessions, and debriefing after the cycle to review successes, challenges, and prep for the next cycle.

### ***Replication-specific factors***

Adaptations and participant engagement go hand in hand: Program implementers, for the most part, made adaptations to programs to tailor the program to participant needs or to satisfy school constraints. Examples of adaptations include: adding material on oral contraception, turning activities into games, replacing videos with some they deemed to be more culturally appropriate, reducing content to conform to time constraints, and adding a PowerPoint to deliver the program for visual learners. In general, those who felt comfortable making adaptations to the program to address participant needs were more experienced in working with youth and delivering programs compared to those that were less experienced. Program implementers reported how important it is to be flexible, both with the program participants and with their stakeholders:

*I think that number one something that really worked was sort of the personalities of the facilitators. They are so good at what they're doing, and they're so adaptable, and easygoing, and I think they really relate to the kid...If you have that really strict personality, that can't really roll with the changes, I think you would really struggle. And I think the kids notice that, and I think they prefer sort of the other way.*

## **DISCUSSION**

Program implementers in this study reported a number of multilevel factors affecting the implementation of evidence-based programs that cut across six different evidence-based programs and implementing organizations. Relationship building with community partner sites and responsiveness to student questions were identified as strategies to address the challenges of implementation. The participant-implementer relationship is often unaccounted and underestimated by program planners (at the management level),<sup>31</sup> therefore planners often do not build in time for creating that relationship. Implementers also pointed to the strength and need for components that address upstream factors related to STD/HIV prevention, such as healthy relationships and childhood abuse. To date and to our knowledge, there is no evidence based SRH curriculum in the United States that directly addresses childhood sexual abuse.

The present analyses also shed light on the restriction program implementers felt in responding to participant needs and addressing curriculum shortages, due to the perceived need to adhere to the prescribed program, and lack of time to complete the curriculum. This limited the autonomy and creativity of program implementers who had experience and training engaging with adolescents. This finding echoes Morrison's study in which program implementer feelings of ownership and creativity with evidence-based programs decreased from the initial implementation of the program to its replication.<sup>32</sup>

The reporting of adaptation data as part of the larger evaluation emerged as an additional factor that increased implementer adherence to the curriculum for some program implementers. The evaluation team defined an adaptation as any change made to the program, whether minor or major, in order to capture all activities implementers were adjusting to adapt the program in a real world setting, however program implementers viewed adaptations as negative and major. In addition, the checkboxes provided in the fidelity logs allowed for three categories: completed, completed with changes, and not completed. Often, program implementers did not consider adjustments to the program as a “change.” The evaluation team made efforts in both writing and in training to encourage recording all changes and to ensure implementers that their fidelity reports would not be used as monitoring tools, yet some lack of clarity around adaptations remained. This finding has important implications for implementation research as researchers should be mindful of the impact the larger perception of adaptations may have on the data. In addition, the developer-created fidelity tools may need to be expanded on in order to capture the wide variety of adjustments that a program implementer can make during implementation and thereby reduce social desirability bias.

### **Limitations and Strengths**

This study was conducted in New Jersey, and the social contexts and educational expectations may therefore not be generalizable to other geographic locations or settings. A limitation of the present study is that some of the themes may have emerged because of the parent evaluation study in the context of a broader national evaluation. The parent evaluation study collected information about implementation and adaptations and the

broader national evaluation provided specific guidance about minimizing adaptations and monitored these at the state level. This study, however, does shed light on how a funder context and evaluation can impact implementation, which may prove more important as replication studies are increasingly researched. The strategies and challenges identified by program implementers may be applicable to a wide array of evidence based adolescent health programs, outside of sexual reproductive health, that employ the use of a curriculum and a facilitator.

## **Conclusion**

The dialogue around adaptations and fidelity within evidence based programs in the research and practice community often prioritizes fidelity, yet the research on the importance of fidelity<sup>33–39</sup> and shortcomings of adaptations is mixed.<sup>35,40–42</sup> Given that adaptations do occur<sup>6,17,40</sup> and implementers report tension adhering to the curriculum as prescribed, future trainings on evidence based programs might consider a paradigm where evidence, facilitator experience, and participant population are all considered before implementation. Additionally, adolescent-specific programming should consider the potential variability in the physical, social, emotional and cognitive development during this age, the need and strength of including components outside STD/HIV messages, such as healthy relationships and abuse, and consider program assumptions regarding adolescent biology knowledge, modes of communication, and type of sexual relationships.

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## **6. ADDRESSING THE ADHERENCE-ADAPTATION DEBATE: LESSONS FROM THE REPLICATION OF AN EVIDENCE-BASED SEXUAL REPRODUCTIVE HEALTH PROGRAM**

### **INTRODUCTION**

In the nation's largest coordinated effort in the adolescent pregnancy prevention, the Family Youth and Services Bureau (FYSB) and the Office of Adolescent Health (OAH), provided over one billion dollars for the scale up and replication of adolescent sexual reproductive health evidence based programs (SRH-EBPs) since 2009.<sup>1,2</sup> This effort presents a great opportunity for replication testing and for the investigation of implementation factors that may shed light on null or enhanced program effects. Studies investigating implementation factors in evidence-based programs have been limited among SRH-EBPs and generally among adolescents; most studies have been conducted among adults in the substance use, mental health, and physical health fields.<sup>3,4</sup>

One implementation outcome is the “fidelity of implementation,” which is defined as the extent to which a program is executed as prescribed by design.<sup>5</sup> Two important dimensions of implementation fidelity include adherence and adaptation.<sup>4,6</sup> Adherence is defined as faithfulness to the core content of a program.<sup>5-8</sup> Adaptation is defined as any modification to a program, inclusive of both modifications that make the program suitable for its context as well as partial completion of activity. This is differentiated from lack of fidelity, which is skipping or not completing an activity in full.<sup>9-11</sup> Adaptations may be made to the content delivered, the way in which the content was delivered, or in the system of delivery.<sup>9</sup> Because implementation conditions in initial evidence-based

setting cannot be replicated exactly in subsequent settings, studies that measure adaptation unfailingly report adaptations during the replication of EBPs.<sup>4,12,13</sup>

We chose to focus on adherence and adaptation because there a debate in the field of implementation science regarding whether adherence is essential and whether adaptations negatively affect program outcomes.<sup>14</sup> Proponents of adherence suggest that higher levels of adherence result in greater program outcomes<sup>10,15–19</sup>, maintaining that adaptations are likely to be reactive and contribute negatively to program effectiveness<sup>13,20</sup>. Proponents of adaptations suggest that adaptations that respond to the local context are necessary and inevitable<sup>7,21</sup>; and, they advocate that adaptations made to suit the local context positively affect program outcomes.<sup>10,22–25</sup> The debate may be in part due to variability in the definitions employed for adherence and adaptation and to poor measurement, often retrospective measurement, of adherence and adaptation. Researchers and program developers are attempting to resolve some of the adherence-adaptation debate through a movement to blend the two views by defining a program's core components and considering adaptations appropriate if they do not interfere with the core components.<sup>20,26,27</sup>

There have been a number of limitations in prior studies examining adaptations and adherence. Prior studies have calculated frequencies of adherence and adaptations, listed type of adaptations, or linked adherence/adaptation scores to program outcomes, but rarely have studies conducted all three.<sup>23,27–31</sup> There are many types of adaptations and varied definitions of adaptations. Without understanding the type of adaptation, conclusions about adaptations are made without context. The objective of the present study was to determine: 1) the frequency of adherence and adaptations in the

implementation of an SRB-EBP, *Making Proud Choices*; 2) the type and rationale for adaptations made; and 3) program outcomes (i.e. knowledge and behavioral intent) for intervention program participants, as compared to comparison participants, by the level of adaptations made in the classroom (high/middle/ low adaptation). This study employed an innovative statistical approach and in-depth mixed methods to explore the adherence-adaptation relationship.

## **METHODS**

### **Study Overview**

The present implementation study was part of a larger quasi-experimental parent evaluation study conducted from 2013-2015. In the parent study, the Johns Hopkins Center for Child and Community Health Research (CCHR) evaluated six evidence-based sexual reproductive health programs implemented by six organizations as a part of the New Jersey Department of Health Personal Responsibility Education Program (NJPREP). The evaluation and implementation study was conducted from 2013-2015. The organizations selected one SRH-EBP to implement from a list of EBPs deemed as ready for widespread replication by the OAH.<sup>32</sup> The EBPs provided information to adolescents on abstinence and contraception, as well as healthy relationships, attitudes and values about adolescent growth, financial literacy, parent-child communication and job success. A requirement of funding was that at least half of program participants resided in communities of high teen pregnancy and STI prevalence. The programs were

implemented in school and community-based settings among 2,698 primarily African American and Hispanic adolescents, ages 10-19 years,

One program site from the parent study was selected to participate in the implementation study: *Making Proud Choices*. The program site was selected based on completion of fidelity logs (i.e. no missing entries), a robust sample size to detect between group effects, variability in implementation measures, and fewer than 5% of activities omitted entirely (to ensure that the relationship tested between adaptations and program outcomes was not confounded by omission of content). The Johns Hopkins School of Medicine Institutional Review Board reviewed and approved all study protocols.

### **Evidence Based Program**

*Making Proud Choices* is a HIV/STI/pregnancy prevention program emphasizing safe sex and abstinence, based on the Social Cognitive Theory. This program is an adaptation of *Be Proud Be Responsible* for adolescents 11-13 years. It consists of 8 one-hour modules and addresses future goals, consequences of HIV/STI/pregnancy, beliefs and attitudes around HIV/STI and condom use, strategies for preventing HIV infection, and condom use and negotiation skills. The program is delivered through group discussions, role-play, games, videos, and exercises. The program can be implemented in two-day, four-day, or eight-day formats. The developer recommends that the entire intervention be completed within 2 weeks, if possible, in either school or community based settings.

### **Study Design**

The evaluation design included matched intervention and comparison groups at the classroom level. The program was implemented in 46 classrooms school-based settings, with at least 50% of participants recruited from the following high-risk communities: Irvington, Jersey City, Newark, Passaic, Paterson, Orange, East Orange and Englewood. First, the intervention group was recruited. Then, comparison group was recruited based on similarity in geographic location and grade. In some cases, the comparison group was recruited from the same school, if allowed. In instances where school officials did not want to split up a grade, comparison participants were recruited from the grade below. And, in some cases comparison participants were recruited from another school in the same town. Participants in the comparison group received educational information on a non-sexual topic. Intervention and comparison participants received two free movie tickets for the completion of three-month follow-up surveys.

### **Data Collection**

Study staff collected demographic and outcome data by administering surveys to participants at pre- and post-test. The survey data was then manually entered into REDCap, an online data collection software by the study staff on a quarterly basis. Adherence and adaptation data was captured via a fidelity log, which was created by the program developer. This log was specific to activities of *Making Proud Choices* and represented all required activities for the program. It was used for each classroom of students with which the intervention was delivered. The program facilitator who delivered the session completed the log within 48 hours after a session was delivered.



The fidelity log was comprised of 34 activities: for which a facilitator marked 1) ‘completely finished activity’ 2) ‘finished activity with changes’ or 3) ‘did not finish activity’. The choices were mutually exclusive and a facilitator could not mark more than one option per activity. Each time a program facilitator marked ‘finished activity with changes’, a text box appeared prompting the facilitator to describe and explain rationale for changes made. This data was also entered into REDCap.

In order to limit social desirability bias, a training on how to fill out fidelity logs was conducted in which the following information was iterated verbally and in written form on the log: “We are looking for honest reports more than perfect reports as we are examining how both fidelity and adaptations work in the real world. Any adaptations, modifications, or changes to the program should be described and explained in as much detail as possible. The more feedback provided, the more helpful these tools will be to us and future implementers.” In the training, program facilitators were instructed to mark anything that deviated from the prescribed program as a change or ‘adaptation’.

## **Measures**

### *Implementation Measures*

Adherence is measured as a percent of the number of times the program facilitator selected the box ‘completely finished’ out of the total number of activities offered (n=34).

Adaptation is measured as a percent of the number of times the program facilitator selected ‘finished activity with changes’ out of the total number of activities offered (n=34).

Non-completion or omission is measured as a percent of the number of times the program facilitator selected “did not finish activity” out of the total number of activities offered (n=34). For the purposes of this study, non completion or omission is not considered an adaptation, rather it is considered lack of fidelity.

Attendance is measured as a percent of the number of sessions an individual attended out of the total number of sessions delivered by an implementer in a classroom. The total number of sessions delivered differed by classroom and implementation setting.

### *Program Outcome Measures*

The evaluation included a survey that was administered to program participants at pre- and post-test. There were two primary outcomes of interest: sexual reproductive health knowledge and behavioral intent. All program outcome measures for this study were assessed at post-test. The post survey was prepared by Mathematica Policy Research, with additional questions measuring sexual reproductive health knowledge added by CCHR. The responses were self-reported by participants.

*Sexual reproductive health knowledge* was measured at pre- and post-test. A refined scale of 9 items were used to create a composite score of knowledge. Questions included five true/false items about behaviors that put you at risk for getting HIV (e.g. sharing needles for tattooing and piercing), four items regarding effective methods to protect people from STDs and pregnancy (e.g. douching) with three choice answers (Protects from Pregnancy & HIV/STD, Protects from Pregnancy Only, Protects from Neither). A composite knowledge continuous score was created for each individual, as percentage of items answered correctly out of the total number of items. Higher scores represented greater sexual reproductive health knowledge.

*Behavioral intent* questions were measured only at post test for both intervention and comparison groups and used a 5 pt Likert scale (much more likely to much less likely). Intent questions for contraception also included an option '*I will abstain from sexual intercourse in the next six months*'. Questions measuring behavior intent were: i) likely to use or ask a partner to use birth control in next 6 months ii) likely to use or ask a partner to use condoms in next 6 months iii) likely to abstain from sexual intercourse in next 6 months. These variables were dichotomized (i.e. 1: more likely 0: same or less likely) in analyses to allow for easier interpretation with a logistic regression. Condom use and birth control intent was measured among the relevant population for this outcome i.e. those adolescents that did were intending to be sexually active.

#### *Independent Variables and Covariates*

Demographics assessed include: i) age (continuous), ii) ethnicity, iii) race, iv) gender v) mother's education

Baseline risky sexual behavior includes: ever had sex (yes/no), ever pregnant (yes/no), sex in the past three months (yes/no), sexual reproductive health knowledge composite score at pre test (continuous), condom use in the past three months (all the time, most of the time, some of the time, none of the time), birth control use in the past three months (all the time, most of the time, some of the time, none of the time).

Social emotional competence measures include: resisted or said no to peer pressure (all of the time- none of the time), cared about doing well in school (all of the time- none of the time), shared things that matter with a parent/guardian (all of the time- none of the time), managed conflict without causing more conflict (all of the time- none of the time).

### **Data Analysis**

All statistical analyses were conducted using STATA 12.0, R (MatchIt) software, and Atlasti.<sup>33</sup> Data analysis procedures are described by objective.

Objective 1: Using fidelity log entries, frequency calculations were conducted for three categories: adherence to core content, adaptation, and non-completion of core content.

Objective 2: All fidelity logs were exported from REDcap and entered into Atlas.ti qualitative software. Fidelity logs were coded and analyzed for emerging categories by

two trained qualitative study team members through an iterative process of co-developing a codebook, coding transcripts independently, reconciling differences through discussion, and jointly developing categories.<sup>34,35</sup>

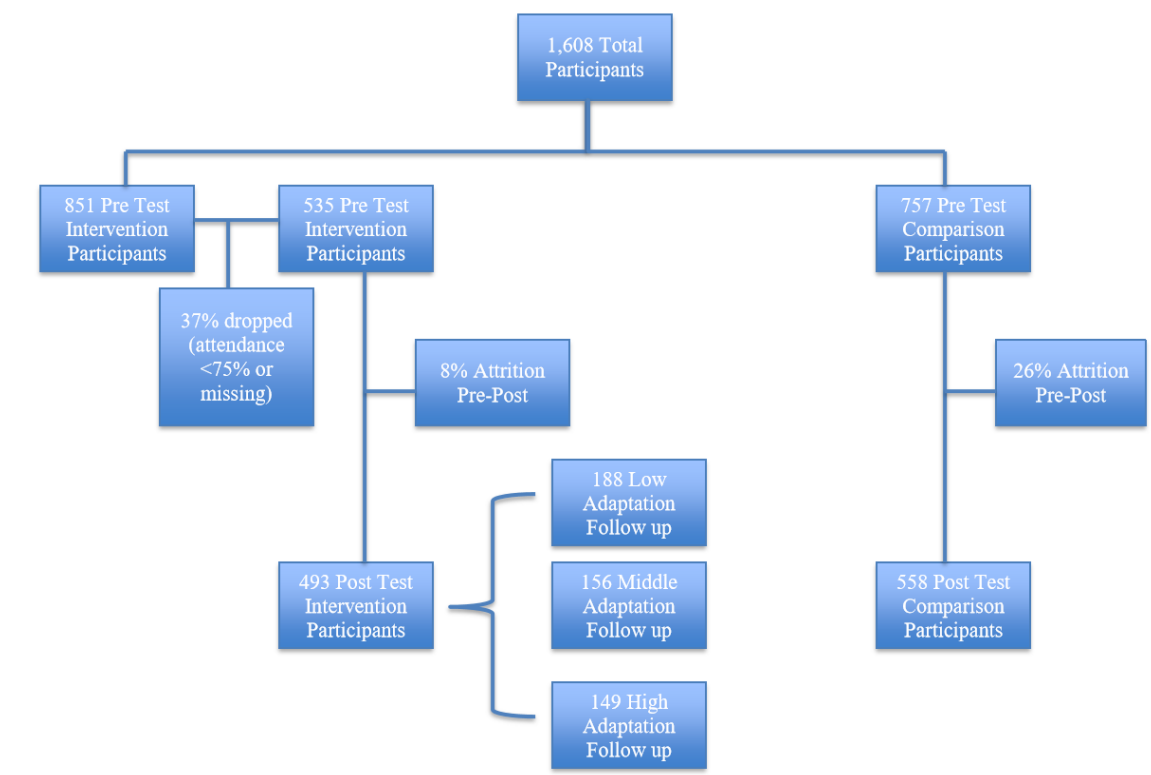
Objective 3: Scale (item analysis) and reliability testing were conducted on two SRH knowledge scales (total of 11 items) related to pregnancy, HIV, and STI acquisition and protection. Item analysis indicated participants answered two of the items incorrectly at a much higher percentage than other items, so they were dropped from the scale.

Cronbach's alpha, a coefficient of internal consistency, was used to estimate reliability.<sup>36</sup> The resulting scale had a reliability of .723, considered sufficient internal consistency.

To determine if adaptations had an effect on program outcomes, three subgroups were created: low adaptation (adaptation <25%), middle adaptation (adaptation between 25-50%), and high adaptation (adaptation >50%). These subgroups were chosen based on distribution of % adherence among classrooms. To our knowledge, there is limited literature on adaptation level and results, however adherence levels were documented so adherence was used as the cutoff. Durlak and Dupre's review of implementation literature report that positive results were found with fidelity levels between 60%-80%.<sup>4</sup> For this reason, the low adaptation/high adherence group was set as greater than 75% adherence, which can also be understood as less than 25% adaptation. To obtain cutoffs for the other two subgroups, the histogram and sample size was taken into consideration to create equal groups at natural cutoffs.

High participant attendance is statistically associated with greater participant program outcomes.<sup>37</sup> Given the link between attendance and program outcomes and the difference in mean attendance in each of the three subgroups, two analyses were conducted so to ensure program outcomes by adaptation subgroup were not affected by attendance in the subgroup: the primary analysis in which participants with less than 75% attendance or missing attendance (<10% missing) were excluded and a sensitivity analysis including all participants. Only participants in the intervention and comparison groups who completed the post test survey were included in analyses of post test outcomes (knowledge/behavioral intent) (i.e. participants who did not answer post test were dropped from the analyses). See **Figure 1** for final sample size and attrition for preliminary analysis.

**Figure 1: Sample Size and Attrition for NJPREP implementation of Making Proud Choices from 2013-2015, N=1,608**



Propensity score matching methods were used to create comparability between adaptation subgroup participants and comparison participants.<sup>38,39</sup> The reason for using a propensity score approach is to account for individual characteristics that may make it more likely for a participant to be in a particular adaptation subgroup. Propensity score matching creates matched groups based on a number of covariates that have been condensed to a single propensity score.<sup>39</sup> A propensity score is defined as “the probability of being in the treatment [intervention] group given observed covariates.”<sup>40</sup> In this case, observed covariates used for matching included: all demographic variables (age/gender/race/ethnicity/SES), baseline sex variables (ever sex/ever pregnant/baseline SRH knowledge score/sex in past three months/birth control use in past three months/condom use past three months), and baseline social emotional competence (resisted peer pressure/cared about school/shared with a parent or guardian/ managed conflict) because these covariates have demonstrated links to program outcomes in the literature.<sup>41,42</sup>

To estimate the program outcomes for each subgroup, the following steps were conducted:

1. Fitted a propensity score model of an adaptation subgroup (low/medium/high adaptation) as a function of covariates, using the adaptation subgroup from the intervention group and the full comparison group.
2. Used full matching to match treatment group members to control group members with similar propensity scores. Full matching creates matched sets of intervention:

control participants. For example, the intervention participant receives a weight of 1 and matched control units receive weights in proportion to the intervention participant so that the covariate distributions between the intervention participant and matched set of control participants are similar.<sup>43</sup> Full matching makes use of all the individuals in the data and has been shown to be effective at reducing bias due to observed confounding variables.<sup>39</sup>

3. Checked the standardized mean difference, indicating the balance of covariates in the matched intervention and comparison groups. If any covariates had standardized differences greater than .20, they were controlled for in the outcome model.
4. Fit a model of the outcome as a function of adaptation subgroup and covariates, with the full matching weights. Differences in mean knowledge score were calculated in addition to the outcome model.
5. Repeated steps 1-4 with remaining two adaptation subgroups

Less than 0.1% of fidelity data was missing and for these values, a value of “completed fully” was entered. Less than 6% of the outcome variables, among those who answered the post test, had missing data. Only variables for which outcome variables were observed were used in analysis.<sup>44</sup> Covariates are required to have a non-missing value in R software prior to propensity score matching. *Missingness* for covariates ranged from 1%-22%. For covariates with missing values, the mean score of the covariate was imputed prior to propensity score matching. For variables with >10% missingness, a dummy variable was created for that variable (0/1) and included in the propensity score



model so that patterns of *missingness* were matched in the propensity score analyses. Because the participants were nested within classrooms, clustering was accounted for at the classroom level to account for participant outcomes being correlated within a classroom. For missing cases in the composite SRH knowledge score, in instances where 1-3 items in the scale were missing, the observed items were used to create the score. If a participant did not respond to more than three items in the scale, the composite SRH knowledge score was coded as missing.

## RESULTS

### Study Population

*Making Proud Choices* was implemented with 1243 participants (685 intervention and 558 control participants). Table 1 represents high attendance ( $\geq 75\%$ ) intervention participants stratified into low, medium, and high adaptation subgroups, and the comparison participants, at post test. High attenders did not portray significant differences in baseline sexual risk behaviors as compared to those who had missing or low attendance in the intervention group, differing significantly only on report of mother's education, reporting "greater than a GED/hs education" (47% versus 39%). Participants in both the intervention and control group who answered the pre test, but did not answer the post test had significantly greater percent distribution of males (58% vs. 49%), and greater percent of African Americans (59% vs 43%), greater percentage of participants who had ever had sex at baseline (29% vs 21%) and a greater percentage of participants who used a condom at last sex at baseline (21% vs 16%).

In total, participants were, on average, 14.8 years ( $SD=.06$ ), 51% female, 45% African American and 17% Caucasian, and 40% Hispanic. At baseline, roughly 19% of the participants had ever had sex, with 15% of total participants having sex in the past three months. At baseline, fewer than 10% of participants always used birth control or condoms. At baseline, less than 20% of participants always shared things with a parent or guardian or were able to manage conflict.

**Table 1** also demonstrates significant differences in key baseline covariates between each of the adaptation groups (low, middle, and high) and the comparison group. Significant differences in baseline covariates are indicated by +. Propensity score matching resulted in no significant differences in baseline covariates between the adaptation subgroup and comparison group.

**Table 1: Baseline Characteristics for Participants in Low, Middle, and High Adaptation Groups at Post Test who attended 75% of the sessions as part of NJPREP, Making Proud Choices, N=1,052**

	Low Adaptation n=188	Middle Adaptation n: 156	High Adaptation n: 149	Comparison n: 558	Total N: 1,052
<b>Demographics</b>					
Age, mean (SD)	15.15 (.15)	14.58 (.17)	14.27 (.18)+	14.93 (.08)	14.82 (.06)
Gender, n (%)					
Male	95 (50)	81 (52)	65 (44)	271 (49)	515 (49)
Female	94 (50)	74 (47)	84 (56)	285(51)	537 (51)
Race, n(%)					
African American	97 (51)+	80 (51)	66 (44)	227 (41)	471 (45)
Caucasian	29 (15)+	27 (17)	26 (17)	97 (17)	181 (17)
Asian	10 (5)+	14 (9)	7 (5)	66 (12)	97 (9)
Native American	14 (7)+	9 (6)	12 (8)	31 (6)	66 (6)
Hawaiian	9 (5)+	3 (2)	13 (9)	33(6)	58 (6)
Ethnicity, n(%)					
Hispanic	75 (40)	50 (32)	76 (51) +	213 (38)	416 (40)
Mother's education, n(%)					
Less than hs	29 (15)+	20 (13)+	19 (13)+	75 (13)	144 (14)
HS/GED	54 (29)+	36 (23)+	49 (33)+	123 (22)	262 (25)
More than hs/GED	85 (45)+	88 (56)+	62 (41)+	237 (42)	473 (45)
<b>Sexual knowledge and behavior</b>					
SRH Knowledge, mean (SD)	77% (.02)	70% (.02)	69% (.02)+	73% (.01)	72% (.01)
Sexual intercourse, ever, n(%)	54 (29)+	31 (20)+	21 (14)+	92 (17)	198 (19)
Pregnancy, ever, n(%)	2 (1)	0 (0)	3 (2)+	3 (1)	5 (1)
Sexual intercourse, past three months, n(%)	44(23)+	25 (16)	19 (13)+	68 (12)	156 (15)
<b>Among the sexually active...</b>					
Birth control past 3 months, always, n(%)	14(7)+	14(9)	10(7)	29 (5)	67 (6)
Condom use past 3 months, always, n(%)	21(11)+	14(9)	11(7)	38(7)	84 (8)
<b>Social emotional competence</b>					
Cared about doing well in school, always	107 (57)+	82 (53)+	85 (57)+	246 (44)	522 (49)
Said no to peer pressure, always	63 (33)+	38 (24)+	44 (30)	166 (30)	312 (30)

Shared with parent/guardian, always	28 (15)	31 (20)	36 (24)+	89 (16)	184 (17)
Managed conflict without causing more, always	45 (24)+	20 (13)+	27 (18)	95 (17)	187 (18)

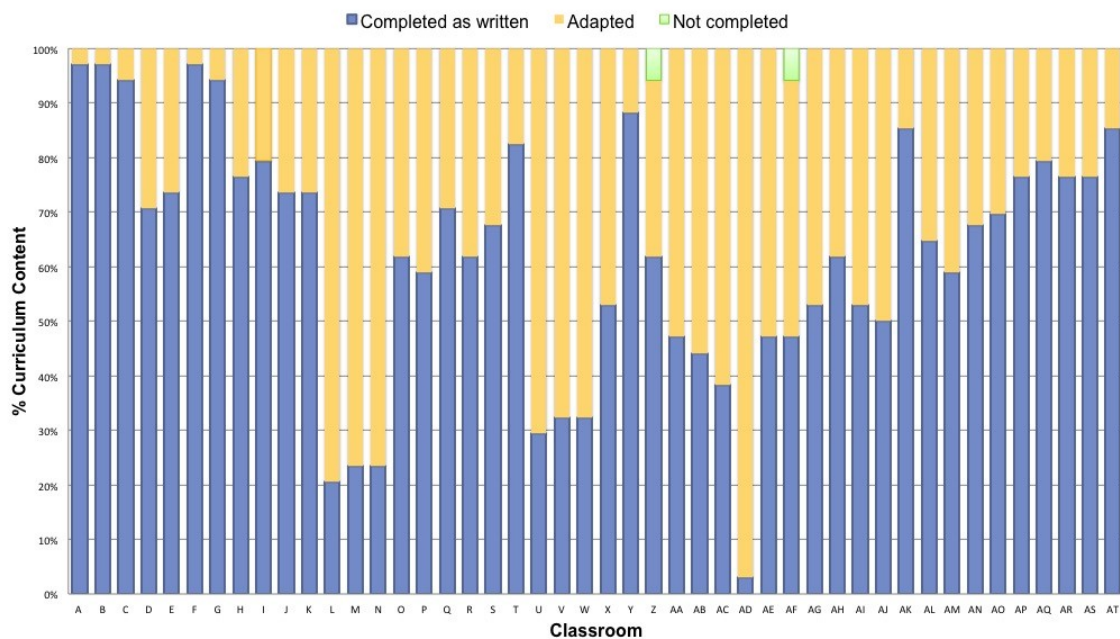
+ significantly different ( $p \leq .05$ ) from comparison group pre matching

++ significantly different from comparison group post matching. Note: all covariates successfully matched post matching

## Frequency of adherence and adaptation to program core components

Percent adaptations to core content in classrooms ranged from 3% to 98%, with a mean adaptation of 63% (see **Figure 2**). Mean adherence was 37%. Percent non-completion was below 6% across all classrooms.

**Figure 2: Description of Adherence and Adaptation to Program Core Content of Implementation of NJPREP, Making Proud Choices from 2013-2015, N=46 classrooms, 685 Intervention Participants**



## Type and Rationale for Adaptations made

**Table 2** indicates types of and rationale for adaptations made, along with associated frequencies. The majority of adaptations made were related to an increase in dosage (i.e.

frequency and length of sessions), both in the number of sessions and in overall time to complete the program. On average, it took facilitators 11 hours to complete the 8-hour program. One reason for this is there was not enough time to deliver program content in the allotted time prescribed by the program. There were additional behavioral issues that required stopping the class and school constraints (i.e. fire drills, previous classes running late, limited classroom space) that took away from time to teach. The second most common adaptation involved changing the way the activity was presented to the group; and this was due as well primarily to time constraints or participant behavior. For example, instead of having students cross a room in order to agree with a true or false statement, implementers had students raise their hands. Or, instead of playing a game, facilitators explored a topic through discussion. Less than 7% of adaptation involved not completing the content, due to either time constraints or lack of student participation. Five percent of the adaptations were related to translation of modules so that all Spanish speaking students could understand the lessons. Another five percent of adaptations involved adding contraceptive models to the lesson.

**Table 2: Type and Rationale for Adaptation made in NPREP, Making Proud Choices, 2013-2015**

Types of Adaptations		Reasons for Adaptations	%
<ul style="list-style-type: none"> <li>Increased number of sessions/time to complete content (<i>on average, it took facilitators ~11 hours and to complete the 8 hour curriculum</i>)</li> </ul>	52.9%	<ul style="list-style-type: none"> <li>Lack of time</li> </ul>	32.4%
<ul style="list-style-type: none"> <li>Changed activity modality (<i>i.e. changed the method of delivering information from written to verbal activity or from a game to discussion</i>)</li> </ul>	14.8%	<ul style="list-style-type: none"> <li>Behavior Management</li> </ul>	21.6%
<ul style="list-style-type: none"> <li>Activity partially completed (<i>i.e. did not complete all role plays</i>)</li> </ul>	6.9%	<ul style="list-style-type: none"> <li>School constraints</li> </ul>	11.6%
<ul style="list-style-type: none"> <li>Translated modules into Spanish</li> </ul>	5.1%	<ul style="list-style-type: none"> <li>Questions from students</li> </ul>	6.4%
<ul style="list-style-type: none"> <li>Added contraceptive models to pass around</li> </ul>	4.7%	<ul style="list-style-type: none"> <li>Facilitator did not bring/use curriculum supplies</li> </ul>	6.4%
<ul style="list-style-type: none"> <li>Other (<i>change in activity sequence, class started late</i>)</li> </ul>	8.0%	<ul style="list-style-type: none"> <li>Other (<i>too few students in class, AV technology not working, IEP inclusion group</i>)</li> </ul>	21.6%

### Comparing Program Outcomes for Low, Middle, and High Adaptation Groups

There were significant differences in mean attendance at the  $p < .05$  level for the three adaptation subgroups [ $F = 9.57$ ,  $p = 0.001$ ]. Post hoc comparisons using the Tukey HSD Test showed that the mean attendance score for the high adaptation subgroup ( $M = .80$ ) was significantly different than the middle ( $M = .84$ ) or low adaptation subgroup ( $M = .87$ ), however there were no significant differences between the middle or low adaptation subgroup. After accounting for attendance, there were no significant differences in mean attendance for the three subgroups of adaptation. **Table 3** represents results, selecting for high attendance. Program outcomes comparing the intervention condition to the comparison condition for the low, middle, and high adaptation groups, respectively, were as follows: differences in SRH knowledge score intervention vs control [low=+14.3%, middle=+17.4% , high=17.8%], intent to use birth control in next 6 months [low: OR= 2.29 (1.28-4.09),  $p = .01$ ; middle: OR= 2.36 (1.09-4.13),  $p = .01$ ; high: OR= 5.67 ( 2.51-

12.85),  $p=.00$ ]; intent to abstain from sex [low: OR=1.63 (.80-3.30),  $p=.17$ ; middle: OR=1.43 (.79-2.61),  $p=.23$ ; high: OR=1.34 (.69-2.63),  $p=.37$ ]; intent to use condoms in the next 6 months [low: OR= 2.04 (1.11-3.76),  $p=.04$ ; middle: OR= 2.36 (1.09-4.13),  $p=.04$ ; high: OR= 5.67 (2.51-12.85),  $p=.04$ ].

**Table 3: Program Outcomes for Low, Middle, and High Adaptation Groups among High Attenders in NJPREP, Making Proud Choices, 2013-2015**

	<b>Low Adaptation</b> Adaptation <25% Attendance >=75%	<b>Middle Adaptation</b> Adaptation 25%-50% Attendance >=75%	<b>High Adaptation</b> Adaptation >50% Attendance >=75%
	Mean adherence: 84.41% Mean adaptation: 15.59%	Mean adherence: 65.64% Mean adaptation: 34.12%	Mean adherence: 37.6% Mean adaptation: 62.0%
Post Test SRH Outcomes	Intervention n: 188 Comparison n: 558	Intervention n: 156 Comparison n: 558	Intervention n: 149 Comparison n: 558
Knowledge % correct Intv vs control/ % difference	89.7% vs. 75.4% + <b>14.3%</b>	86.6% vs. 69.2% + <b>17.4%</b>	86.9% vs. 69.1% + <b>17.8%</b>
Intent to abstain from sex in next 6 months	OR: 1.63 (.80-3.30) $p=.17$	OR: 1.43(.79-2.61) $p=.23$	OR: 1.34 (.69-2.63) $p=.37$
Among those who do not plan to abstain...	Intervention: 101 Comparison: 298	Intervention: 102 Comparison: 298	Intervention: 89 Comparison: 298
Intent to use birth control (including condoms) in next 6 months	<b>OR: 2.29 (1.28-4.09)</b> <b>p=.01</b>	<b>OR: 2.36 (1.09-4.13)</b> <b>P=.01</b>	<b>OR: 5.67 (2.51-12.85)</b> <b>p=.00</b>
Intent to use condoms in next 6 months	<b>OR: 2.04 (1.11-3.76)</b> <b>P=.04</b>	<b>OR: 1.96 (1.05-3.66)</b> <b>P=.04</b>	<b>OR: 3.10 (1.01-9.51)</b> <b>P=.04</b>

**Table 4** represents sensitivity analysis results including all participants, regardless of attendance status. Program outcomes comparing the intervention condition to the comparison condition for the low, middle, and high adaptation groups, respectively, were as follows: differences in SRH knowledge score intervention vs control [low=+11.6%,

middle=+15.0% , high=14.2%], intent to use birth control in next 6 months [low: OR= 1.93 (1.18-3.16), p=.01; middle: OR= 2.06 (1.14-3.76), p=.02; high: OR= 3.49 (1.80-6.76), p=.00]; intent to abstain from sex [low: OR=1.86 (.95-3.63), p=.07; middle: OR=1.60 (.86-2.96), p=.13; high: OR=1.59 (.81-3.13), p=.17]; intent to use condoms in the next 6 months [low: OR= 1.48 (.91-2.40), p=.11; middle: OR= 1.71 (.93-3.11), p=.08; high: OR= 3.03 (1.21-7.63), p=.01].

**Table 4: Sensitivity Analysis: Program Outcomes for Low, Middle, and High Adaptation Groups among All Attenders in NJPREP, Making Proud Choices, 2013-2015**

	<b>Low Adaptation</b> Adherence >=75%	<b>Middle Adaptation</b> Adherence 50%-75%	<b>High Adaptation</b> Adherence <=50%
	Mean adherence: 84.22% Mean adaptation: 15.78%	Mean adherence: 65.64% Mean adaptation: 34.12%	Mean adherence: 37.6% Mean adaptation: 62.0%
Post Test SRH Outcomes	Intervention n: 244 Comparison n: 558	Intervention n: 211 Comparison n: 558	Intervention n: 234 Comparison n: 558
Knowledge % correct Intv vs control/ % difference	88.3% vs. 76.7% + <b>11.6%</b>	85.2% vs. 70.2% + <b>15.0%</b>	83.3% vs. 69.1% + <b>14.2%</b>
Intent to abstain from sex in next 6 months	OR: 1.86 (.95-3.63) p=.07	OR: 1.60(.86-2.96) p=.13	OR: 1.59 (.81-3.13) p=.17
Among those who do not plan to abstain...	Intervention: 159 Comparison: 280	Intervention: 145 Comparison: 280	Intervention: 137 Comparison: 280
Intent to use birth control (including condoms) in next 6 months	<b>OR: 1.93 (1.18-3.16)</b> <b>p=.01</b>	<b>OR: 2.06 (1.14-3.76)</b> <b>P=.02</b>	<b>OR: 3.49 (1.80-6.76)</b> <b>P=.00</b>
Intent to use condoms in next 6 months	OR: 1.48 (.91-2.40) P=.11	OR: 1.71 (.93-3.11) P=.08	<b>OR: 3.03 (1.21-7.63)</b> <b>P=.01</b>

## DISCUSSION

The objective of the present study was to determine: 1) the frequency of adherence and adaptations in the implementation of an SRB-EBP, *Making Proud Choices*; 2) the type



and rationale for adaptations made; and 3) program outcomes (i.e. knowledge and behavioral intent) for intervention program participants, as compared to comparison participants, by the level of adaptations made in the classroom (high/middle/ low adaptation). Results indicate there is variability in frequency of adaptations made and percent adaptations made, by classroom. The type of adaptations suggest that program implementers were not making changes to core content of the program, but rather were making changes in delivery of the content (stylistic changes) such as dosage (i.e. frequency and length of sessions), modality, and adding props- largely as a response to classroom context and participant need/behavior. This data suggests there is high completion of core content, but not without some changes to the delivery of content. The data also suggest that the program facilitators were aware of the importance to adhere to other program components such as dosage and pedagogy, and marked any deviation from these core components as an adaptation. This is likely due, in part, to the reiteration of the evaluation team to note any deviation from the prescribed program on the fidelity log.

As compared to the control condition, level of adaptation (low, middle and high) produces similar program outcomes in knowledge, intent to abstain, and intent to use birth control, as compared to the control participants; and the high adaptation subgroup does not appear to negatively affect program outcomes. This is not surprising, given the nature and type of adaptations being made. The adaptations made were largely a reaction to time constraints and student environment. In the sensitivity analyses including all participants, however, the high adaptation subgroup produces significant intent to use a condom, as compared to the control condition, while the middle and low adaptation

subgroups do not. This is also in line with the hypothesis that intervention participants in the high adaptation subgroup due not appear to have reduced program outcomes. An argument in the larger debate is that planned adaptations are appropriate and unplanned adaptations are inappropriate, however, as evidenced by this data, not all adaptations were planned; for example, student behavioral issues and late arrival of students are not always anticipated. It is important to note that the implementation team was able schedule extra time to complete the program with partner sites; however, this may not always be the case. Planning for more sessions than the required program dosage may be an appropriate planned adaptation for future program implementers.

Given that adaptations do and will occur, our findings support the argument for allowing facilitators some flexibility and autonomy to adapt the delivery of content of EBPs to participant needs and setting constraints. In creating flexibility, some more work will need to be done both with developers and in trainings of EBPs. Developers themselves are not entirely clear on what activities are necessary and what could be omitted under time constraints.<sup>45</sup> EBP trainings as is, however, do not include or require extensive training on how to make adaptations or proactively plan for them, and implementers and investigators alike have noted that they “struggled with the process of adaptation.”<sup>46,47</sup> Program implementers are often instructed to contact the program developer regarding adaptations they would like to make, rather than being taught the theory behind intervention fidelity and adaptation, and building self-efficacy to adapt the program to program developer standards.<sup>48</sup> This is particularly problematic for implementers who are often making adaptations in real time to adapt to unpredictable contexts and behaviors

within the classroom. Incorporating session on “how to” make pedagogical adaptations, for example, or how to plan for increasing dosage, or how to handle instances of time constraints and behavior issues might be useful for facilitators.

### **Limitations and Strengths**

Limitations include program implementer self-report of adherence and adaptation data.

The literature is mixed as to whether this data is correlated with observational measures<sup>14,23</sup>; however, as described in the methodology, steps were taken to limit social

desirability bias. This study was conducted within a funding environment of the Office of Adolescent Health where fidelity was encouraged. Additionally, this program was implemented in a school-based setting, so adherence/adaptation frequencies;

generalization beyond that setting is not warranted. Types of adaptations may differ in other contexts. This study does not suggest that adaptations of any nature do not appear to affect program outcomes; rather that adaptations of this particular nature and frequency listed in this study do not appear to reduce program outcomes.

Prior studies<sup>23,28,29</sup> examining adaptations and fidelity calculate frequencies of fidelity and adaptations, list type of adaptations, or link fidelity/adaptation scores to program outcomes- this study utilizes a mixed methods approach to address all three aspects of prior studies, adjusting for program attendance. Additionally, adherence and adaptation data was collected 48 hours after every session, limiting recall bias. Lastly, because implementation data are often not collected for comparison groups, analyses linking implementation to program outcomes do not include control groups in analyses- resulting

in descriptive analyses. This study employed an innovative propensity score matching approach to utilize both implementation and control participants, so that causal inferences can be made regarding program outcomes.

## **Conclusion**

These findings support a flexible, blended view of adherence and adaptation, and suggest a movement away from the delineation of adaptations as ‘good’ or ‘bad,’ and instead taking into consideration their complexity in nature. Measuring both rationale (intent) and type of adaptation made is crucial to understanding the complexity of adaptations. This study illuminates the importance of future studies measuring the type and rationale for adaptations made to appropriately understand their influence on program outcomes. As implementation and replication science moves forward, it is important to measure implementation in standard evaluation practice of EBPs in order to continue to understand the complexity of adaptations and their contribution to replication findings.

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## CONCLUSIONS

### Summary of Findings

This work examined the implementation of a statewide replication of six different SRH EBPs via three aims: 1) quantitatively assessing the psychometric properties of a participant responsiveness questions asked on a national survey of SRH EBPs in this study 2) qualitatively understanding the multilevel factors that result in implementation successes and challenges of SRH EBPs, from the perspectives of the program implementers, and 3) qualitatively and quantitatively documenting adherence and adaptation data for a SRH EBP and linking this implementation data to participant program outcomes. The goal of this work was to contribute to implementation and replication science literature. Findings from each of the chapters are highlighted below:

Because the implementation science is a developing field, measurement work is necessary and essential.<sup>1,2</sup> Chapter 4 presented a refined measure of participant responsiveness, demonstrating both the measure's utility among the adolescent population of mixed age, gender, and race and its invariance across different evidence based programs and settings. This chapter also revealed high participant responsiveness scores across all SRH EBPs, suggesting strong participant receptivity to and engagement in SRH EBPs.

In Chapter 5, program implementers identified multilevel facilitating and challenging factors to implementation of evidence based programs, cutting across six different evidence based models and implementing organizations. Relationship building with

partner sites and participants were identified as strategies critical for implementation success. Program implementers, however, felt challenged in implementing some of these strategies, which required adaptations, due to perceived need to maintain fidelity to the program.

Chapter 6 demonstrated that adherence and adaptation varied considerably by classroom, supporting that adaptation is largely dependent on participant needs and setting constraints. Adaptations made were related to delivery of content, rather than to the content itself. Adaptations were made to response to participant needs and setting constraints. The findings suggest that participants in classrooms of high adaptation did not appear to have reduced program outcomes.

## **Implications**

### *Public Health*

These findings support the argument for allowing facilitators some flexibility and autonomy to adapt the delivery of prescribed content of EBPs to participant needs and setting constraints. Having built in flexibility into the curriculum, a training on how to make adaptations, and a larger funder support for blended view of adherence and adaptation may potentially allow for more successful implementation.

Curriculum: SRH EBP developers may consider including the following components to future updates of their curricula: healthy and unhealthy relationships, rapport building, and flexibility (i.e. allow for facilitator adaptations such as implementing specific components of the program based on the needs of their youth). Qualitative data in this study suggested that Teen Outreach Program may serve as a model for flexibility in programming.

EBP training: EBP trainings currently do not include or require extensive training on how to make adaptations or proactively plan for them, and implementers and investigators alike have noted that they “struggled with the process of adaptation.”<sup>3,4</sup> Training may be conducted “how to” make adaptations for various scenarios such as behavior issues, participant lack of interest, participant questions, and time constraints with partner sites.

Funding and evaluation community: The larger funding and evaluation community might consider changing the dialogue around adaptations away from the delineation of adaptations as ‘good’ or ‘bad,’ to incorporating a flexible, blended view of adherence and adaptation, taking into consideration the complexity of adaptations. Understanding both rationale (intent) and type of adaptation made is crucial to understanding the complexity of adaptations. Program implementer perception of the term “adaptation” as negative may prevent facilitators from using their natural abilities to make acceptable adaptations to enhance the program curriculum, increase participant engagement, and potentially increase program effectiveness.

### *Research*

While this study utilized developer-created fidelity logs, our qualitative data suggested that these fidelity logs are not stand alone and require training. Predefined categories such as ‘completed’ ‘completed with changes’ and ‘not completed’ became elusive when a program implementer is unclear or assumes the definition of a “change.”

Implementation researchers may set the stage for what a ‘change’ is in relation to evaluation or research objectives. As an example, program developers of EBPs in the field of sexual risk reduction have identified core components of curriculum and some

work has been done nationally to categorize adaptations into ‘green’, ‘yellow’, and ‘red light’ adaptations.<sup>5,6</sup> Green adaptations are considered ‘safe’ and may include updating statistics, customizing role plays. Yellow adaptations may include adding activities or changing the order of activities, while red adaptations include shortening a program or eliminating activities. Some program implementers may only mark an activity as a ‘change’ if it falls into the red category. If researchers are interested in the wide array of adaptations being made (green, yellow, or red), then program implementers must be trained to mark *any* deviation from the program as a change (as was done in this study). Similarly, if researchers are interested in only red adaptations, then a ‘change’ must be defined in that way. The limitation of current developer-created fidelity logs is that there is only one column represented for changes. A potential remedy would be to expand the log to include a dropdown menu of type of change (i.e. shorted lesson, eliminated activities, changed role plays, added content) so that a wide array of adaptations could be indicated and there would be less reliance on the evaluator definition of adaptation or program implementer interpretation of an adaptation. As implementation research may be increasingly important in evaluation research, it is imperative that fidelity logs are precise, accurate, and stand alone. As mentioned previously, adaptations are complex in nature. Measuring both rationale (intent) and type of adaptation made is crucial to understanding the complexity of adaptations and their influence on program outcomes.

While this work focused on central implementation components (adherence, adaptations, and participant responsiveness), there are other implementation components such as quality of delivery, and participant population factors (race, gender, and sexual risk), study design, outcome measurement that may contribute to difference in replication

findings. It is not clear if or what the prescribed importance should be of each of these factors to replication success. As replication findings emerge, Goesling cautions against making overly simplistic conclusions about replication findings.<sup>7</sup> Without reproducing the exact implementation and evaluation conditions of the initial setting, he suggests, one should not expect to see the same results.<sup>7</sup>

The designation of SRH programs as evidence based typically relies on a single efficacy study alone that demonstrates behavior change in participants. With the substantial nationwide scale up and replication of SRH EBPs, perhaps we might consider redefining what is considered evidence-based to include findings from replication studies. The next question is then which kind of study is more important to consider for broad dissemination--replication studies because they mimic real world conditions or initial efficacy studies because they control for external factors? Or, is it a combination of both?

The Office of Adolescent Health reorganized EBP selection for their second round of TPP funding based on evaluation findings from the first cohort. For example, EBPs were eliminated for selection for the following reasons: negative findings, three or more high quality studies that were unable to replicate initial efficacy results, and evidence 20 years old or more.<sup>8</sup> This may be a model for redefinition for the term ‘evidence-based.’ Even with a strong evaluation design, it remains difficult to know if replication findings are the result of implementation or program theory without implementation research as part of evaluation research. As the field moves forward and the evidence builds, perhaps our definition of what it means to be evidence-based will move with it and redefined on a broader scale.

As we move forward, it is important and critical to include implementation in standard evaluation practice of EBPs in order to continue to build the evidence base and test program theory.

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## APPENDICES

### Appendix I: Facilitator Interview Guide Facilitator Interview Guide

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Time: \_\_\_\_: \_\_\_\_ AM/PM

Interviewer Initials: \_\_\_\_

Grantee: \_\_\_\_\_

Facilitator Initials: \_\_\_\_

*Thank you so much for being part of this interview. We consider you the expert so I'm so excited to talk to you. Your responses will be so valuable to the field of implementation and evidence based models. Just wanted to remind you that your confidentiality and privacy will be protected. I am the only one sitting in the call right now and nothing you say here today will linked back to you. After this call, your interview will be transcribed and any identifying information will be removed. NO right or wrong answers, we just want to learn from you.*

#### Background

1. Tell me about your school and work background (Additional probes: please describe any experiences facilitating or working with low income youth prior to your current role). What motivated you to get into this field versus any other field?
2. How did you get involved in [insert model name]? What interested you to get involved? What pulled you in to this program? (Probes: how long have you been working with [insert model name]?) Done EBP before?

#### Current Role

3. Describe your current job as a facilitator (workload, what a typical week is like, your overall experiences being a facilitator). – would you do it again?
4. What training, if any, did you receive to implement [insert model name] and how useful was that for your current role. Explain.

#### Theory of Change

5. What do you think the core components of the [insert model name] are? In other words, what goes into the program to make it effective?
6. How do you think this program works to prevent teen pregnancy?

#### View of the Model

7. How do you personally feel about the program curriculum and model? (Additional probes: What do you consider the strengths of the program curriculum to be? What do you consider the weaknesses of the program curriculum to be?)
8. How did the community respond to the program? (i.e. how did partners, parents, schools respond to the program)

9. How did the participants or students respond to the program?
10. What would your ideal teen pregnancy prevention model look like? What would it consist of?

*Moving on to our next section. We know that adaptations of the evidence-based model occur during implementation in order to fit the needs of the community and constraints your organization is working under. We are interested in seeing how you have used adaptations in the implementation of the model.*

#### Adaptations- Filling out the logs

11. How do you define an adaptation?
12. Describe the protocol used to fill out the fidelity forms and under what circumstances each box (completed with changes/completed/not completed) was checked.
  - a. In what cases did you mark the box “completed with changes” versus “completed” on your fidelity form?
  - b. If the developer approved an adaptation, did you still mark “completed with changes?”
  - c. If you added content, how was this indicated in the fidelity logs (in check box or in open commentary space)?
  - d. Were you consistent in your protocol for filling out these forms throughout the data collection cycle?

#### Adaptations- Descriptions and Process

13. Describe what it was like to stick to the curriculum.
14. What, if any, issues arose in sticking to the curriculum and what did you do to respond?
15. What is one of the more major changes or deviations from the program curriculum and tell me about how that happened?
16. I’m interested in planned and unplanned changes from the curriculum. Can you tell me more about the changes that were planned vs unplanned and how they came about?

#### Recommendations

17. Discuss three things that worked in implementation of the program curriculum?
18. Discuss three challenges in implementation of the program curriculum?
19. Discuss three recommendations you would have to future facilitators of this program?



## Appendix II: Program Manager Interview Guide

### Program Manager Interview Guide

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_\_  
Time: \_\_\_\_:\_\_\_\_ AM/PM  
Interviewer Initials: \_\_\_\_ \_\_\_\_  
Grantee: \_\_\_\_\_  
Facilitator Initials: \_\_\_\_ \_\_\_\_

*Thank you so much for being part of this interview. We consider you the expert so I'm so excited to talk to you. Your responses will be so valuable to the field of implementation and evidence based models. Just wanted to remind you that your confidentiality and privacy will be protected. I am the only one sitting in the call right now and nothing you say here today will linked back to you. After this call, your interview will be transcribed and any identifying information will be removed. There are no right or wrong answers, we just want to learn from you.*

#### Grantee Background

1. Tell me about your organization (how long has it been around, who does it serve).
2. How did you get involved in organization [insert model name]? What interested you to get involved? What pulled you in to this program? *Passion* (Probes: how long have you been working with [insert model name]?)
3. Why did your organization apply for this grant?
4. How did you pick [insert evidence based model name]? What made [insert evidence based model name] appealing?

#### Grantee and Program Congruence

5. Thinking back, how well did this program align with your organization's mission? (Probes: Did it strengthen it or end up being a diversion? Does this program facilitate your other work? Does it put you in a better position moving forward or does it make it more complicated?)

-Have you implemented an evidence model before?

-Training received

#### Community Support

6. How did the community respond to the program? (i.e. how did partners, parents)
7. How did the participants or students respond to the program?

CBO/SBO difference? In implementation?

Ask about other programs in the community?

*Now, we will focus more on the curriculum and then go into your personal views of the curriculum*

#### Theory of Change

8. What do you think the core components of *[insert model name]* are? In other words, what goes into the program to make it effective?
9. How do you think [the program] work to prevent teen pregnancy? **revise**

#### View of the Model

10. How do you personally feel about the program curriculum and model?  
(Additional probes: What do you consider the strengths of the program curriculum to be? What do you consider the weaknesses of the program curriculum to be?)
11. What would your ideal teen pregnancy prevention model look like? What would it consist of? If you had all the money in the world. I know this is a big question.

*Moving on to our next section. We know that adaptations of the evidence-based model occur during implementation in order to fit the needs of the community and constraints your organization is working under. We are interested in seeing how you have used adaptations in the implementation of the model.*

#### Adaptations- Filling out logs- prelude this

12. How do you define an adaptation?
13. Describe the protocol used to fill out the fidelity forms and under what circumstances each box (completed with changes/completed/not completed) was checked. Generally speaking,
  - a. In what cases did you mark the box “completed with changes” versus “completed” on your fidelity form?
  - b. If the developer approved an adaptation, did you still mark “completed with changes?”
  - c. If you added anything activities or content, how was this indicated in the fidelity logs (in check box or in open commentary space)?
  - d. Were you consistent in your protocol for filling out these forms throughout the data collection cycle?

#### Adaptation- Descriptions and Processes

14. Describe what it was like to stick to the curriculum.- deliver as prescribed? what were the things you would've done if you didn't need to stick to the curriculum?
15. What, if any, issues arose in sticking to the curriculum and what did you do to respond? Ask for examples...
16. What is one of the changes or deviations from the program curriculum and tell me about how that happened?
17. I'm interested in planned and unplanned changes from the curriculum. Can you tell me more about the changes that were planned vs unplanned and how they came about?
18. For fidelity- context balance?

#### Resources

19. Did you feel like you and your staff put in more time and resources than you were covered?
20. Turnover

Control Groups

20. Please describe the materials or sessions delivered to your control groups.

Recommendations- off the top of your head and you can take a minute to think about this

21. Discuss three things that worked in delivery of program curriculum?
22. Discuss three challenges in delivering the program curriculum?
23. Discuss three recommendations you would have to future facilitators of this program?

## Appendix III: Written Consent



Date: July 3, 2014  
Principal Investigator: Jacky Jennings  
Application No.: NA\_00084099

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient ID: \_\_\_\_\_

### RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

**Protocol Title:** Evaluation of the New Jersey Personal Responsibility Education Program (PREP)

**Application No.:** NA\_00084099

**Sponsor:** Department of Health and Human Services

**Principal Investigator:** Jacky Jennings,  
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Baltimore, Maryland, 21224  
Phone: 410-550-4132 Fax: 410-550-4153

#### 1. What you should know about this study:

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Please ask questions at any time about anything you do not understand.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- If you receive routine medical treatment (including medical or laboratory tests) in the study or if you are taking part in the study at the Clinical Research Unit, information about your research study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- The Johns Hopkins School of Medicine Institutional Review Board (IRB) sometimes reviews studies that are conducted at other institutions. These other institutions are solely responsible for conducting

the study safely and according to the protocol that the Johns Hopkins IRB has approved. Information about how to contact the investigator at the institution that is responsible for the study is included in this form. When another institution is conducting the study, the word "we" in this consent form may include both Johns Hopkins and the participating institution.

**2. Why is this research being done?**

This research is being done to learn about facilitators' and program managers' experiences in implementing an evidence-based model. Our understanding of how evidence based models actually work in the real world relies on our understanding of implementation of these models.

We plan to conduct interviews with people who are working on the ground and in organizations involved in implementing evidence based models. We want to get a better understanding of how these models work in the real world from facilitators and program managers whose knowledge and expertise would be very valuable to future implementers and researchers.

People who served as facilitators or program managers of implementing these models may join this research.

**How many people will be in this study?**

About 20 people will be in this study.

**3. What will happen if you join this study?**

If you agree to be in this study, we will ask you to do the following things:

**Answer questions related to:**

- your role in implementation of the project
- your opinions of the model
- your understanding fidelity and adaptations to the model
- the technical assistance and training you received
- how decisions were made in implementation of the program
- overall challenges, successes, and recommendations of implementing the model

**Where is the interview?**

The interview will occur at your implementation site, if possible, or by phone.

**Will the interview be recorded?**

Because we want to accurately capture all you have to say, we will digitally record your interview. Only the project research assistant will hear the recording and you will not be identified by name. At the end of the study, all recordings will be destroyed. Only people who work on this project will be able to see the transcript of your interview, and your name will not be used in anything we write.

**How long will the interview last?**

The interview will last between 40 and 60 minutes.

**How long will you be in the study?**

You will be in this study for one day.

**4. What are the risks or discomforts of the study?**

There are no significant risks associated with being interviewed; it is simply an opportunity for us to learn from your expertise as an implementer of evidence based models. While there are no significant risks, there may be a time burden as well as discomfort for sensitive questions.

There is a risk that information about you could become known to people outside of this study. Personal identifying information should not get discussed in the interview, however if it does get discussed in the interview, it will be deleted in the transcripts. The digital recordings will also be kept locked in our researcher's office and will be destroyed after the data has been analyzed.

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

**5. Are there benefits to being in the study?**

There is no direct benefit to you from being in this study. If you take part in this study, you may help contribute to the knowledge base of replication of evidence based programs research and providing insight for future implementers.

**6. What are your options if you do not want to be in the study?**

An alternative is to not take part in the study. You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

**7. Will it cost you anything to be in this study?**

No.

**8. Will you be paid if you join this study?**

No.

**9. Can you leave the study early?**

You can agree to be in the study now, and change your mind later. If you wish to leave the study early, please tell us.

If you leave the study early, Johns Hopkins may use or give out your health information they have already collected if the information is needed for this study or any follow-up activities.

**10. How will your privacy be protected?**

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information

available to your doctors for your safety. If you think this study might affect your clinical care, please inform your doctor.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

**11. What other things should you know about this research study?**

**a. What is the Institutional Review Board (IRB) and how does it protect you?**

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

**b. What do you do if you have questions about the study?**

Call the principal investigator, Dr. Jacky Jennings at 410-550-4132. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

**c. What happens to data that is collected in the study?**

Johns Hopkins and our research partners work to understand and cure diseases. The data you provide is important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.



**12. What does your signature on this consent form mean?**

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

**WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM**

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Signature of Participant (Print Name) Date/Time

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Signature of Person Obtaining Consent (Print Name) Date/Time

**NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD.**

**ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.**

# JENITA PAREKH, MPH, PhD

[jenita.parekh@gmail.com](mailto:jenita.parekh@gmail.com)

281.660.0471

## SUMMARY

- Eight years of experience conducting public health and social science research, specializing in both qualitative and quantitative methods, with particular strengths in managing evaluation, implementation, and community based participatory research (CBPR) studies
- Extensive knowledge of evidence based programs, adolescent sexual and reproductive health, youth development, evaluation methods, and CBPR theory.
- Extensive experience with specialized evaluation analysis methods (i.e. propensity score matching), implementation measurement development, qualitative research design, quasi experimental design studies, conducting in depth interviews (50+) and focus groups (+40), conducting qualitative data analysis workshops with community members, managing CBPR studies, and working collaboratively with community partners and funders.
- Collaborative with strong leadership, written and verbal communication skills
- Proficient in Stata, Atlasti, R, Microsoft Office

## EDUCATION

**Johns Hopkins Bloomberg School of Public Health**, Baltimore, MD August 2016  
**PhD** in department of Population, Family, and Reproductive Health  
Dissertation Title: Implementation and Replication of Evidence Based Sexual Risk Reduction Programs for Adolescents

**The University of Texas School of Public Health**, Houston, TX May 2009  
**Masters in Public Health**, Community Health Practice  
Thesis Title: Youth Empowerment Evaluation to Improve Afterschool Programming, using an empowerment evaluation model and community-based participatory approach.

**The University of Texas at Austin**, Austin, TX August 2005  
B.A. Plan II Liberal Arts Honors Program

## TRAINING GRANTS

National Institutes of Health Training Grant (NIAID T32 AI050056-1) Sept 2014- Sept 2015

Maternal and Child Health Training Grant May 2011- 2013

## RESEARCH EXPERIENCE

**Johns Hopkins University**, Baltimore, MD  
**Graduate Research Assistant**

**Center for Child and Community Research, School of Medicine** Oct 2011- present  
Evaluation of evidence based sexual risk reduction programs in New Jersey

- Wrote the proposal to accrue funding for project (HHS-2010-ACF-ACYF-PREP-0125)
- Managed data collection
- Conceptualized and developed implementation measures for the evaluation
- Conducted quantitative analysis measuring effect of programs, incorporating implementation data and using propensity score matching, paper in progress
- Conducted psychometric testing on implementation measures
- Conceptualized study design, created survey guide, pilot tested guide, conducted in depth interviews, led qualitative analysis, and wrote publication titled ““You can get more out of a kid if you're able to stray a little bit”: Program implementer perspectives delivering evidence-based sexual reproductive health programs to adolescents”
- Conducted statistical analysis on drug use and networks in adolescents, coauthored paper and poster (P.I. Jacky Jennings)

**Center for Adolescent Health** Dec 2011-Dec 2013

- Conducted qualitative analysis on interview data for study on vulnerable adolescents and violence in Baltimore (P.I. Kristin Mmari)
- Conducted quantitative analysis on health of military youth (P.I. Bob Blum)

**Department of Population, Family, and Reproductive Health** Feb 2013- Jan 2014

- Supervised participatory groups for intervention development for female sex workers (P.I.: Michele Decker)
- Conceptualized and conducted a systematic review of evidence based comprehensive programs for youth (P.I. Bob Blum), resulting in publication
- Conducted an evaluation of the Incentive Mentoring Program (P.I. Kristin Mmari)

**Federal Reviewer for Office of Adolescent Health, Washington DC** Feb 2015

- Reviewed competitive funding applications for OASH Tier 1b teen pregnancy prevention programs and participated in panel evaluation of grants

**St. Luke's Episcopal Health Charities, Houston, TX** April 2008-Aug 2011

Center for Community-Based Research

**Senior Research Associate** May 2009-Aug 2011

- Developed qualitative and quantitative instruments
- Developed record keeping procedures for the Center
- Conducted focus groups
- Managed data collection activities

- Managed three Community Research Teams (10-13 ppl/team)
- Led qualitative data analysis trainings and meetings
- Co-authored research reports

Above activities were performed for each of the studies below:

Avon Breast Health Study: Co-Investigator

Partnered with Rose to determine barriers for mammography screening among low income Africa American women, using mixed methods and a community-based participatory approach

Komen: Fort Bend County Breast Health Assessment

Conducted a breast health assessment of Fort Bend County using mixed methods and a community-based participatory approach

CDC SIP: Intervention Research on Youth Development to Prevent Teen Pregnancy

Evaluated the program at mid and end points of the year, using an empowerment evaluation model and community-based participatory approach

Evaluation of Aids Foundation Houston's Teen Leadership Forum

Evaluated the Forum using an empowerment evaluation model and a community-based participatory approach

City of Houston: Disaster Preparedness of Vulnerable Populations in Houston

Conducted a community-based participatory research project to investigate public health preparedness issues in vulnerable populations in Houston, follow up to 2008 study

**Research Assistant**

April 2008- May 2009

- Conducted and led qualitative analysis
- Developed qualitative instruments
- Supervised participatory groups

Above activities were performed for each of the studies below:

City of Houston: Disaster Preparedness of Vulnerable Populations in Houston

Conducted a community-based participatory research project to investigate public health preparedness issues in vulnerable populations in Houston

CDC SIP: Intervention Research on Youth Development to Prevent Teen Pregnancy

Evaluated the youth development pregnancy prevention program at midpoint of the year, using an empowerment evaluation model and community-based participatory approach.

**PUBLIC HEALTH WORK EXPERIENCE**

**Americorps, Houston, TX**

Jan. 2007- Aug 2007

Gateway to Care Navigator

700 hours served

Assisted underprivileged clients access healthcare and social service needs

Led planning of 'Health Topic of the Month' project for Legacy Clinic including the proposal, survey, results and analysis report, and implementation of the first 'Health Topic of the Month'

**AVSAR, Bombay, India**

June 2005 – Aug 2005

Summer Intern-Volunteer

Worked with Apnalya, an NGO in Bombay directed towards improving community health in slums.

Participated weekly formal public health discussions with AVSAR team of 7 people to help gain better understanding of the community health situation and areas of focus within slums

Collaborated with local NGOs in Bombay to help create a network to attain joint goals

Made home visits with community health workers to gain awareness of common health issues within community as well as methods to help patients

Assisted in creating and editing yearly health reports capturing the current state of the health within slums

Created a pamphlet on adolescent and women's sexual health to help educate women within the community on STI prevention techniques

**Citizen's Schools, Houston, TX**

Sept. 2006 – May 2007

Citizen Teacher

Jan. 2007 – May 2007

Teaching Associate

Sept. 2006- Dec.

2006

Created weekly curriculum for a class of 10 students to improve studying skills, team building activities, and leadership and provided daily academic coaching through Citizen's Schools, a national organization geared towards preparing students in grades 6 – 8 for higher education and career development

Taught weekly stock market apprenticeship and art apprenticeship to help create greater awareness of financial career opportunities and to introduce complex art techniques that culminated in the creation of a mural, respectively

Attended daily staff meetings to prepare for the day and address and improve issues such as attendance and motivational techniques

## **TEACHING ASSISTANTSHIPS**

Johns Hopkins Bloomberg School of Public Health

Program Evaluation

Spring 2013

Global Health Principles and Practice

Spring 2014

## **COMMITTEES/ EDITORIAL BOARDS**

**Johns Hopkins Bloomberg School of Public Health**

Associate Editor for Progress in Community Health Partnerships 2015	Mar 2013- Mar
Search Committee for Director for Center of Adolescent Health 2013	Mar 2012- Mar
Doctoral Admissions Committee 2015	Dec 2014- Mar
Community Research Advisory Council 2014	Mar 2012- Jan

**University of Texas at Houston School of Public Health Student Association**

Executive Director	Apr 2008-Apr 2009
Academic Council Representative	Sept. 2007- Apr 2008

**PEER REVIEWED PUBLICATIONS**

Kågesten A, **Parekh J**, Tunçalp O, Turke S, and Robert William Blum. Comprehensive Adolescent Health Programs That Include Sexual and Reproductive Health Services: A Systematic Review. American Journal of Public Health: December 2014, Vol. 104, No. 12, pp. e23-e36.

Polk S, Ellen J, Fichtenberg C, Huettner S; Reilly, M; **Parekh J**; Jennings, J.  
“Identifying and characterizing places for the targeted control of HIV in urban areas.” AIDS and Behavior.

Leifheit K, **Parekh J**, Matson P, Moulton L, Ellen J, and Jacky M. Jennings Is the Association between Neighborhood Drug Prevalence and Marijuana use Independent of Peer Drug and Alcohol Norms? Results from a Household Survey of Urban Youth Journal of Urban Health. Aug 2015, Vol. 92: 773-783

**REPORTS**

**Parekh, J.**, Lopez, K. Peranteau, J., May, M. Aids Foundation Teen Leadership Forum Empowerment Evaluation Report. Prepared for Aids Foundation Houston. November 2009.

Peranteau, J., Bush, T., **Parekh, J.**, May, M., Ford, M., Lopez, K., Bray, G. Public Health and Disaster Preparedness of Vulnerable Populations in Houston. Report prepared for Houston Department of Health and Human Services, Office of Surveillance and Public Health Preparedness. November 2009.

Peranteau, J., Highfield, L., **Parekh, J.**, Bush, T., Balihe, P., Siddqui, Z., Adams, F., Ford, M., Bray, PG. Fort Bend County Breast Health Assessment. June 2010

**PRESENTATIONS**

**Parekh J**, “Assessing Implementation and Effectiveness of Evidence Based Sexual Risk Reduction Programs. Invited guest speaker “Program Evaluation” class at Johns Hopkins Bloomberg School of Public Health, March 2015.

**Parekh, J.**, Greene Yvonne. “Community Research Faculty and Training Curriculum.” Campus Community Partnerships for Health. May 2011.

Highfield Linda, **Parekh J**, May Marlynn. “Mixed Methods Workshop.” Campus Community Partnerships for Health. May 2011.

Highfield Linda, **Parekh J**, Bush Troy. “Komen Breast Health Study.” Campus Community Partnerships for Health. May 2011.

**Parekh, J.**, Lopez, K., Markham, C., Peranteau, J. “Youth Empowerment Evaluation to Improve Afterschool Programming” Oral presentation at the 137th Annual Meeting of American Public Health Association, Philadelphia, PA. 2009.

## **POSTERS**

**Parekh J**, Caldas V, Howard S, Jennings J “Program Implementer Perspectives Delivering Evidence Based Curricula” National Institutes of Health. 8<sup>th</sup> Annual Conference on the Science of Dissemination and Implementation. Dec 15, 2015. Washington, DC.

**Parekh J**, Howard S, Jennings J “Measuring Implementation Quality for Evidence Based Teen Pregnancy Prevention Programs.” 2014 HHS Teen Pregnancy Prevention Grantee Conference. June 6, 2014. Washington, D.C.

Leifheit K, **Parekh J**, Matson PA, Moulton LH, Ellen J, JM Jennings. “Adolescent and Young Adult Marijuana Use and Sexually Transmitted Infections: Peer Drug and Alcohol Norms Mediate the Association between Neighborhood Drug Prevalence and Marijuana Use.” Presented at the Society for Epidemiologic Research Meeting. June 25<sup>th</sup>, 2014. Seattle, Washington

**Parekh, J.**, Bush W., Peranteau, J. Participatory Evaluation of a Life Skills Program for Youth with HIV/AIDS. Improving Health Through Community Engaged Research, Ann Harbor, Michigan. 2010.

## **MERIT SCHOLARSHIPS**

Omega Leadership Institute	Sept 2015
Cheryl Alexander Memorial	March 2013
Silber Award	March 2012
Susan G. Sampson Scholarship, University of Texas School of Public Health	Aug 2008
Davidson Scholarship, University of Texas at Austin	Fall 2001, Spring 2002